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The UNESCO Genetics and Bioethics Declarations:  
Implications for Global Governance

Thesis submitted for the degree of  
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## **ABSTRACT**

The sequencing of the entire human genome has opened up unprecedented possibilities for healthcare, but also ethical and social dilemmas about how these can be achieved, particularly in developing countries. This thesis examines two of the several international responses these dilemmas have spawned: the suite of declarations on genetics and bioethics adopted between 1997 and 2005 by the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the Global Genomics Initiative proposed by the Toronto Joint Centre for Bioethics (TJCB). Through these initiatives, UNESCO and TJCB hope to promote the ethical governance of genetic and biomedical research, which is often conducted on an international basis. The thesis draws on interview, documentary and observational data, collected in Kenya and South Africa and from UNESCO, to assess the actual and potential efficacy of these two governance mechanisms, in terms of protecting individual research participants and reducing inequalities of health between North and South. It analyses the negotiation and subsequent implementation of the UNESCO declarations at international and national levels and the plans to date for the Global Genomics Initiative. Using as a conceptual framework particular branches of international relations theory concerned with global governance—namely regime theory, networked governance and cosmopolitan democracy—the thesis finds that determining where the balance of power between different actors should lie and, moreover, how this balance can be achieved is complex and difficult in international decision-making fora. Furthermore, the effective implementation of any regulations, policies or programmes there decided upon requires co-ordination among different sectors and organisations, across international and national levels. The thesis concludes that the UNESCO declarations on genetics and bioethics might provide a means to effect such a system of governance, if supported by networks of stakeholders both within and between states, perhaps through the proposed GGI.

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Adèle Langlois, "Crossing Places in Bioethics Regulation: Kenya and Beyond," in *Crossing Places: New Research in African Studies*, edited by Charlotte Baker and Zoë Norridge (Newcastle: Cambridge Scholars Publishing, 2007): 114-127.

Adèle Langlois, "The Governance of Genomic Information: Will It Come of Age?" *Genomics, Society and Policy* 2 (3) (2006): 49-63.

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## **ABBREVIATIONS**

|             |   |
|-------------|---|
| AGPF        | Africa Genome Policy Forum                                  |
| AMCOST      | African Ministerial Council on Science and Technology       |
| BRIC        | Biotechnology Regional Innovation Centre                    |
| CIOMS       | Council for International Organizations of Medical Sciences |
| DNA         | Deoxyribonucleic acid                                       |
| EEP         | Ethics Education Programme                                  |
| ETM         | Electronic town meeting                                     |
| EU          | European Union  |
| GEObs       | Global Ethics Observatory                                   |
| GGI         | Global Genomics Initiative                                  |
| GIN         | Global issues network                                       |
| GPG         | Global public good  |
| GPPN        | Global public policy network                                |
| HUGO        | Human Genome Organisation                                   |
| IBC         | International Bioethics Committee                           |
| IDHGD       | International Declaration on Human Genetic Data             |
| IGBC        | Intergovernmental Bioethics Committee                       |
| IGE meeting | Intergovernmental meeting of experts                        |
| IGO         | Intergovernmental organisation                              |
| IRENSA      | International Research Ethics Network for Southern Africa   |
| KEMRI       | Kenya Medical Research Institute                            |
| NCST        | National Council for Science and Technology                 |
| NEPAD       | New Partnership for Africa's Development                    |
| NGO         | Non-governmental organisation                               |
| REC         | Research ethics committee                                   |
| RNA         | Ribonucleic acid  |
| SARETI      | South African Research Ethics Training Initiative           |



|               |   |
|---------------|---|
| <b>TJCB</b>   | <b>Toronto Joint Centre for Bioethics</b>                               |
| <b>UDBHR</b>  | <b>Universal Declaration on Bioethics and Human Rights</b>              |
| <b>UDHGHR</b> | <b>Universal Declaration on the Human Genome and Human Rights</b>       |
| <b>UN</b>     | <b>United Nations</b>   |
| <b>UNAIDS</b> | <b>Joint United Nations Programme on HIV/AIDS</b>                       |
| <b>UNDP</b>   | <b>United Nations Development Programme</b>                             |
| <b>UNESCO</b> | <b>United Nations Educational, Scientific and Cultural Organization</b> |
| <b>US</b>     | <b>United States (of America)</b>                                       |
| <b>USD</b>    | <b>United States dollar</b>   |
| <b>WHO</b>    | <b>World Health Organization</b>  |

The sequencing of the entire human genome has opened up unprecedented possibilities for healthcare, but also ethical and social dilemmas about how these can be achieved, particularly in developing countries. According to how competently such dilemmas are managed, the fruits of genetic and other biomedical research may exacerbate or reduce inequalities of health between North and South. The effects of these inequalities have the potential to spread beyond national boundaries, hence this is of global import. UNESCO, the United Nations Educational, Scientific and Cultural Organization, has over the last decade adopted a suite of declarations to address such issues, two in the specific field of human genetics and a third on bioethics more generally. As a separate entity, an international network for knowledge sharing and informed decision-making, a Global Genomics Initiative, has also been proposed. Using as a conceptual framework those branches of international relations theory concerned with traditional and more fluid forms of global governance, this thesis examines the actual and potential efficacy of these mechanisms, with a focus on the South. It also looks at the wider implications of genetics and bioethics as a case study for approaches to global governance. This chapter lays out the main argument and structure of the thesis, which aims to answer the following research question:

What insights can international relations theory offer into the actual and potential efficacy of global governance mechanisms in genetics and bioethics, particularly with regard to developing countries?

## **1.1 CONCEPTS AND ARGUMENT**

International relations theory, in its various forms, seeks to explain world affairs and expound how they might, if possible, be better governed. Decision-making on the management of collective issues and the subsequent implementation of regulations and policies constitute governance. At the national level these tasks are often undertaken by

governments. At the international level, however, governance is conducted in the absence of a formal world government, partly through institutions such as UNESCO. 'Global governance' refers to how global issues or problems (those that have the potential to affect everyone, irrespective of national boundaries) are or could be addressed.<sup>1</sup> The effective governance of human genetic and biomedical research would contribute to the protection of individual research participants and, more broadly, the harnessing of this research to tackle the health needs of the South. It would entail, firstly, high quality decisions on how these goals could be achieved and, secondly, comprehensive implementation of those decisions. This thesis argues that the UNESCO declarations on genetics and bioethics, if supported by networks of stakeholders both within and between states, might provide a means to effect such a system of governance.

## **1.2 GENETICS AND BIOETHICS**

Chapter 2 considers why genetics and bioethics are global issues and why they require governance. Genetics is the study of genes, the molecular units which determine various phenotypic characteristics and influence, for example, susceptibility to disease. Genomics concerns the entire sequence of genes found within an organism's genome.<sup>2</sup> The term 'bioethics' can be used to cover ethical issues across a broad spectrum, but for the purposes of this thesis is defined more narrowly as the ethics of biomedical research with human subjects. Both genetic and biomedical research are conducted on a worldwide scale. Genetics presents new ethical problems, or at least new perspectives on existing ones. That members of families and communities may share genes poses a challenge to the established bioethical principles of privacy and confidentiality, for instance. Relatedly,

---

<sup>1</sup> The word 'global' is used to denote issues or entities with the potential to affect everyone. Correspondingly, 'international' applies primarily to relations between nation-states. Note, however, that organisations in which these relations are typical, such as organs of the United Nations, increasingly include non-state actors in their deliberations and activities. The theoretical background to the term 'global governance' is discussed more fully in Chapter 3.

<sup>2</sup> Henceforth, 'genetics' will be used to denote both genetics and genomics. A more detailed explanation of the two terms can be found at 2.2.1.

if the human genome is the common ‘heritage of humanity’, as UNESCO terms it,<sup>3</sup> this raises the question of how the benefits that might accrue from genetic research should be distributed. At the same time, understandings of what constitutes a bioethical concern are broadening. As inequalities in access to medicine and healthcare between North and South enlarge, what should be the focus of research becomes in itself an ethical question (aside from how it should be carried out). Some commentators have suggested that harnessing the potential of genetics to address the health needs of the South could help to reduce these inequalities, while others see a change in attitudes as the necessary catalyst, rather than advances in technology.

### 1.3 GOVERNANCE MECHANISMS

Chapter 2 goes on to describe two initiatives that might provide governance of genetics and bioethics at an international level. UNESCO has spawned three declarations in this regard, the 1997 *Universal Declaration on the Human Genome and Human Rights*, the 2003 *International Declaration on Human Genetic Data* and the 2005 *Universal Declaration on Bioethics and Human Rights*. Each embraces well-established bioethical principles, such as autonomy and informed consent, as well as newer ideals of knowledge sharing and capacity building, particularly between developed and developing countries. The declarations are non-binding in international law, thus the onus is on member states to apply them within their national laws, regulations or policies. UNESCO considers the declarations unique among bioethics instruments because they were agreed by governments. The thesis investigates the significance of this claim for effective governance.

The general inefficacy of existing governance arrangements within the international system has prompted scholars at the Toronto Joint Centre for Bioethics to suggest an

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<sup>3</sup> UNESCO, *Universal Declaration on the Human Genome and Human Rights*, article 1.



alternative governance structure for genetics and bioethics, a Global Genomics Initiative. This would take the form of a network, underpinned by governments but also incorporating stakeholders from academia, civil society and the private sector, with an emphasis on leadership from the South. Like the UNESCO declarations it would encourage knowledge sharing and capacity building and espouse norms for the ethical conduct of genetic research. The thesis considers whether the network's distinctive governance structure would justify its being established in the face of these similarities. It also contemplates whether the two initiatives might be synchronised.

## **1.4 INTERNATIONAL RELATIONS THEORY**

Chapter 3 outlines several approaches to global governance within the field of international relations. These might help to explain the efficacy or otherwise of the UNESCO declarations as a governance mechanism for genetics and bioethics and whether the Global Genomics Initiative (GGI) might provide a viable alternative. They might also suggest how both initiatives could be improved upon, in terms of decision-making and regulatory or programmatic procedures. The chapter focuses on four specific approaches—regime theory, issue-based global networks, government networks and cosmopolitan democracy—chosen for their pertinence to the governance of global issues such as genetics and bioethics and to the UNESCO declarations and the GGI in particular. Regime theory attempts to explain why and how, in a world of sovereign states, collective action arises and is maintained. Regimes thus comprise understandings, formal or informal, between states and other actors, about how agreements on a given issue should be arrived at, what they should include and how they should be implemented. They often entail bargaining, concession and compromise in order to enable consensus. The UNESCO declarations can be considered a formal, non-binding regime.



Together with regime theorists, both scholars and practitioners of global governance have in recent years tried to find ways in which such arrangements might be strengthened or enhanced, in order to address global problems and issues more effectively. They generally advocate involving, to a greater or lesser extent, those with expertise or an interest in the matter at hand, alongside government representatives. Nayef Samhat, for example, argues for greater inclusion of non-state actors in decision-making within international regimes, thus formulating regimes as public spheres, or spaces for dialogue and deliberation.<sup>4</sup> Some of the recent thinking has had a direct impact on the plans for the GGI, which are modelled heavily on the work of Jean-François Rischard and Anne-Marie Slaughter. Both these authors recommend forms of networked governance, but with differences in the balance of influence between state and non-state actors. Rischard proposes partnerships between governments, industry and civil society, whilst Slaughter promotes governance through networks of government officials.<sup>5</sup> More ambitious is the template for cosmopolitan democracy put forward by David Held and Daniele Archibugi, which seeks to locate democracy beyond state borders, in an “array of fora” from the local to the global.<sup>6</sup> Whereas regimes and networked governance would concentrate on single issues, such as genetics and bioethics, cosmopolitan democracy would signify a holistic approach to global governance, situating targeted problem-solving within a broader programme of systemic change.

## 1.5 METHODOLOGY

Chapter 4 outlines how the research question was investigated. A case study approach was adopted, with the UNESCO declarations and the proposed GGI as primary cases and Kenya and South Africa as sub-units. Since the declarations are non-binding, they must be adopted by member states if they are to be implemented effectively. Whether this is

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<sup>4</sup> See Samhat, “International Regimes and the Prospects for Global Democracy,” among his other papers cited in the thesis.

<sup>5</sup> See Rischard, *High Noon* and Slaughter, *A New World Order*.

<sup>6</sup> Held, *Global Covenant*, 115. See also his several papers cited in the thesis, as well as those of Archibugi, such as “Cosmopolitan Democracy and its Critics.”

likely will perhaps depend not only on the usefulness of UNESCO's support programmes and on particular national circumstances, but also on whether states (and individual stakeholders within them) believe they had sufficient input into the content of the declarations. Such questions are also pertinent to the proposed GGI, as if established it would rely partly on its multisectoral membership for legitimacy. Within regime theory, there have been frequent calls for empirical research at national level, in response to the question, "Do regimes matter?" As yet relatively few studies have been conducted, however. With regard to the UNESCO declarations, most analyses have emerged from the discipline of bioethics rather than international relations, but here too the focus has been on their negotiation and content rather than their impact on national ethics policies and systems. Thus the thesis addresses gaps in both the international relations and bioethics literatures.

The empirical research traced relations between actors both vertically and horizontally, in terms of how decisions made internationally translate downwards and how far these processes involve different stakeholders, be they governmental, academic, civic or private. To this end, fieldwork among policy-makers, geneticists, ethicists, civil society representatives and industry professionals was conducted. This produced qualitative data in interview, documentary and observational formats, which were subsequently coded and analysed in function of the approaches to global governance outlined above. Kenya and South Africa were chosen as the major fieldwork destinations because of their significant activities and involvement in genetics and bioethics at local, national, regional and international levels, with a small number of interviews also being carried out in France and the United Kingdom.<sup>7</sup> Chapter 4 outlines the methodology in more detail, including how challenges such as gaining access to participants and meeting ethical requirements were overcome.

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<sup>7</sup> UNESCO headquarters are based in Paris, France. The interviews in the United Kingdom were with people who had attended negotiations for the 2005 UNESCO bioethics declaration.

## 1.6 FINDINGS

The findings are presented thematically, in two chapters. Chapter 5 discusses legitimacy, representation and accountability within the decision-making process for the UNESCO declarations, Chapter 6 the nature of the norms contained therein and how they are being implemented and enforced. Each chapter also explores what might be the prospects for the GGI, if established, based partly on the UNESCO data and partly on responses to interview questions directly concerning the proposed network. In terms of the UNESCO negotiations, relations between states were found to be ostensibly equal, but power differentials between North and South surfaced in spite of formal procedures aimed at containing these. Non-state actors, particularly experts in genetics and bioethics, were involved in the negotiation process to a certain extent, but the hierarchical approach that saw state representatives making the ultimate decisions precipitated a dichotomous tension between these two groups. The tension was mirrored at national level, where in both Kenya and South Africa geneticists and ethicists felt they had not been satisfactorily included in consultations around the draft declarations and that those who had attended the international negotiations were not sufficiently expert in the issues at hand. This affected their perceptions of the declarations' legitimacy, particularly in comparison to that of similar instruments produced by other international bodies. Government officials from those departments and units not directly connected with UNESCO headquarters in Paris, but nevertheless staking a claim in genetics and bioethics, also felt excluded from the negotiation process. Perhaps unsurprisingly given these results, interviewees generally welcomed the GGI proposals, particularly the multisectoral membership and southern leadership aspects. As most of these people had not actually been asked to join the GGI, however, nor indeed had even heard of it, whether it could succeed in fulfilling these plans is open to question.

In terms of implementation and enforcement, the UNESCO declarations exhibit many typical aspects of non-binding regimes. Their non-binding status ensured consensus



among member states was possible, the pay-off being that adherence is consequently harder to ensure. UNESCO is encouraging rather than enforcing compliance, through various activities aimed primarily at building national capacities for implementation of the declarations, including information dissemination and ethics education. Those states that have already adopted some of the principles enshrined in the declarations have not necessarily done so directly. In Kenya and South Africa, for example, recently published national guidelines on bioethics reflect the *Universal Declaration on Bioethics and Human Rights* (2005) in several respects, but were drafted with reference to earlier texts produced by other international bodies rather than the UNESCO declaration. This highlights the duplication of functions and mandates that can occur in the currently *ad hoc* international system. Since the proposed GGI's activities would be similar again, like its intergovernmental counterpart it would have to find a niche in order to make a distinctive impact on the governance of genetics and bioethics. Chapter 6 outlines some of the issues that UNESCO or the GGI might try to address. These issues are particularly pertinent to Kenya and South Africa (and perhaps, by inference, other developing countries) and include the protection of potentially vulnerable research participants and the need for more training in ethical review.

## **1.7 IMPLICATIONS**

The implications of these findings in relation to international relations theory around global governance are discussed in Chapter 7. The discussion is twofold: it considers, firstly, how the governance of genetics and bioethics might be improved through the implementation of aspects of normative regime theory, networked governance or cosmopolitan democracy and, secondly, what governance issues these approaches might fail to address, as revealed by the UNESCO and GGI case studies. In this regard it examines how relations between developed and developing countries can be made more equal; who should be involved in global level decision-making and how this should

proceed; how overlap between initiatives can be avoided; what can be done to improve the implementation of international norms by sovereign states; how far universal norms can be contextualised; and what the impact of national level governance is on the efficacy of that at international level. Chapter 8 draws some conclusions from this discussion, on the implications for global governance in general and for genetics and bioethics in particular. With regard to decision-making, whether and how stakeholders in a given issue and the public at large can be democratically included at international level demand further thought in terms of what make for constructive, fair and incentive procedures. In terms of effective implementation, coordination within and between international and national layers of governance is required. As institutions do not suddenly disappear, any new governance structures would have to be integrated with older ones. For genetics and bioethics, a network built around the UNESCO declarations rather than as an alternative to them might provide a means to combine the positive aspects of both traditional and innovative forms of governance. This would require better communications among actors and a large injection of funding.

This chapter has provided an overview of the thesis. In summary, Chapters 3 and 4 outline the theoretical framework and methodology by which the research question was investigated. Chapters 5 and 6 analyse the empirical data collected. Chapter 7 discusses these findings in function of the theoretical framework and Chapter 8 draws some conclusions based on this discussion. First, though, Chapter 2 introduces genetics and bioethics and particular mechanisms for their governance.



*Every scientific revolution brings with it a host of ethical and social questions. The so-called genetics revolution is no exception, giving rise to a broad international debate on how the undoubted benefits of progress in this area can be reconciled with certain core human values.<sup>1</sup>*

This thesis comprises an analysis of existing and potential mechanisms for the governance of human genetic and biomedical research, from an international relations perspective. Governance in this context refers to attempts to ensure that research is conducted ethically, through the formulation and implementation of regulations, policies and programmes.<sup>2</sup> The UNESCO declarations on genetics and bioethics and the proposed Global Genomics Initiative (GGI) have stemmed from the tremendous increase in the profile of genetics in the light of the sequencing of the human genome and the extension of biomedical research beyond national borders. This chapter introduces the two initiatives and outlines how they seek to facilitate the reconciliation the quote above purports necessary. It begins with a discussion of what is understood by the terms 'bioethics', 'genomics' and 'genetics' and why it is that the issues they cover require governance at local to international levels, particularly with regard to developing countries. It then explores how UNESCO's three declarations and the proposed GGI might provide such governance. A brief introduction to genetics and bioethics in Kenya and South Africa follows, as a prelude to the empirical analyses of Chapters 5 and 6. Drawing together all these strands, the chapter closes with a portrait of what the effective governance of genetic and biomedical research would look like in global terms.

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<sup>1</sup> UNESCO, "Human Genetic Data: Preliminary Study of the IBC," 1.

<sup>2</sup> For a fuller discussion, particularly in terms of 'global governance', see 3.2.

## 2.1 BIOETHICS

### 2.1.1 Background

Bioethics as a field has evolved from two separate disciplines: medical ethics and moral philosophy. Concern for ethics in terms of patient welfare first appeared in the form of the Hippocratic oath, while moral philosophers have come to reflect on dilemmas faced by modern society alongside more abstract meta-ethics.<sup>3</sup> Bioethics is now seen to cover a wide range of issues, including genetics, reproductive technologies and biomedical research. John Harris gives a succinct definition in his introduction to *Bioethics*, part of the *Oxford Readings in Philosophy* series: "In short, bioethics investigates ethical issues arising in the life sciences (medicine, health care, genetics, biology, research, etc) by applying the principles and methods of moral philosophy to these problems."<sup>4</sup>

While the term 'bioethics' can incorporate issues ranging from environmental ethics to animal welfare, this thesis is primarily concerned with the ethics of biomedical research with human subjects. At international level, research ethics were first laid down in regulatory form in 1947, in the Nuremberg Code. This codification was a response to the human rights abuses that had taken place through experimentation on human subjects under the Nazi regime of World War II and enshrined a key principle in bioethics, that of informed consent: a person agreeing to take part in research should do so voluntarily and with sufficient knowledge and understanding of what is involved.<sup>5</sup> The Code also encompasses what have come to be known as the 'four principles' or 'Georgetown principles' formulated by philosophers Tom Beauchamp and James Childress in the 1970s, namely respect for autonomy, non-maleficence, beneficence and justice. Although

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<sup>3</sup> Harris, "The Scope and Importance of Bioethics," 1-2.

<sup>4</sup> Ibid, 4.

<sup>5</sup> Fluss, "The Evolution of Research Ethics," 596-597; National Institutes of Health, "Regulations and Ethical Guidelines," <http://ohsr.od.nih.gov/guidelines/nuremberg.html> (accessed 19 August 2006).



contested, these principles provide a normative framework that is widely used by researchers (and medical practitioners).<sup>6</sup>

There have been several further attempts to codify good research practice, to ensure, as far as possible, that the rights of those who take part in research are protected. In 1964, the World Medical Association produced the *Declaration of Helsinki: Ethical Principles for Medical Research involving Human Subjects*, which reflects the four principles. Updated regularly, most recently in 2000,<sup>7</sup> this is generally considered the foremost document globally on medical research ethics.<sup>8</sup> The *International Ethical Guidelines for Biomedical Research Involving Human Subjects* of the Council for International Organizations of Medical Sciences (CIOMS) are intended to complement the Helsinki declaration. They give guidance on how its principles can be applied, particularly in developing countries.<sup>9</sup> At other levels, many countries and research institutions have their own legal or regulatory instruments on bioethics, albeit usually based to a large extent on one or more of the international documents. The UNESCO declarations are the latest additions to this array. One of the main requirements of these various instruments will usually be that proposed research projects should be reviewed by a research ethics committee (REC).

### **2.1.2 Governance Issues in bioethics**

To ensure that a research project will be conducted ethically, RECs must determine whether the procedures for obtaining informed consent and the predicted risk/benefit ratio will be conducive to the protection of research participants, in terms of privacy, confidentiality, autonomy and safety.<sup>10</sup> How such concerns should be met has warranted renewed reflection in recent years, in the context of the growing frequency of research projects involving more than one country, including developing ones. The need to build

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<sup>6</sup> Beauchamp, "Principlism and its Alleged Competitors," 479-480; Holm, "Not Just Autonomy," 494-495.

<sup>7</sup> World Medical Association, *Declaration of Helsinki*, 1.

<sup>8</sup> Carlson, Boyd and Webb, "The Revision of the Declaration of Helsinki," 695.

<sup>9</sup> CIOMS, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*.

<sup>10</sup> Benatar, "Reflections and Recommendations on Research Ethics in Developing Countries," 1134.

capacity for ethical review in developing countries has also been noted. This section explores these issues.

#### **2.1.2.1 *Universalism versus pluralism***

The extension of biomedical research beyond national borders renders international standards on bioethics necessary, so that research participants are treated equally and fairly whichever country they are from.<sup>11</sup> Sjef Gevers, Giovanni Berlinguer and Solomon Benatar all endorse the establishment of universal ethical norms to encapsulate these standards (see 3.4.1 for more on what is understood by the word 'norm').<sup>12</sup> Since such norms are likely to be realised in different cultures, it is important that their application be contextualised. The Nuffield Council on Bioethics' report on the ethics of healthcare research in developing countries highlights the difficulties that ensue if sponsors fail to familiarise themselves with the cultural traditions of the countries in which they undertake research.<sup>13</sup> Benatar, with Peter Singer, recommends that international researchers should be sensitive to local social, economic and political contexts,<sup>14</sup> while Zulfiqar Bhutta suggests that communities should be involved in decision-making about research to be conducted in their locales.<sup>15</sup>

In a separate article, Benatar stipulates that contextualisation should only go so far: "Respect for democracy should take precedence over the preservation of cultural traditions that undermine democracy and human rights."<sup>16</sup> Others would disagree, believing the idea that universal norms exist at all to be erroneous. "Agreement at the level of general norms has no inherent practical significance since it is possible to derive

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<sup>11</sup> Gevers, "Medical Research Involving Human Subjects," 293.

<sup>12</sup> Ibid; Berlinguer, "Bioethics, Health, and Inequality," 1087; Benatar, "Reflections and Recommendations," 1135.

<sup>13</sup> Nuffield Council on Bioethics, "The Ethics of Research Related to Healthcare in Developing Countries: A Guide to the Report," 2.

<sup>14</sup> Benatar and Singer, "A New Look at International Research Ethics," 826.

<sup>15</sup> Bhutta, "Ethics in International Health Research," 116.

<sup>16</sup> Benatar, "Towards Progress in Resolving Dilemmas in International Research Ethics," 576.



markedly divergent policies and practices from the 'same' principle, maxim, or moral intuition," writes Leigh Turner. She argues that historical and anthropological evidence for a common morality (including the notion of universal human rights) is scarce.<sup>17</sup> Similarly, modern bioethics has been criticised for deeming universal what some consider to be merely Western notions of ethics.<sup>18</sup> The tension between universalism and pluralism in bioethics reflects a wider philosophical debate that is also manifest in international relations theory (see 3.5.4).

### **2.1.2.2 Vulnerability of research subjects**

Medical research is largely market driven, to the detriment of those in poor parts of the world where infectious diseases are rife. A well-known study by Médecins Sans Frontières and the Drugs for Neglected Diseases Initiative showed that of the 1,556 drugs marketed between 1975 and 2004, only 21 are for diseases mainly affecting the South.<sup>19</sup> While those in developing countries have seen relatively little benefit from medical research, they may well have participated in it: open access to patients, lower costs and fewer regulations have produced what Benatar terms a "research sweat shop."<sup>20</sup> Some people in countries with poor healthcare provision may become research participants in order to receive treatment to which they would not normally have access.<sup>21</sup> Berlinguer has warned against medical research becoming a new form of exploitation.<sup>22</sup>

If all research in developing countries was to stop, for fear of exploiting vulnerable populations, the corollary would be that even fewer resources would be devoted to

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<sup>17</sup> Turner, "Zones of Consensus and Zones of Conflict," 194, 195 and 197.

<sup>18</sup> Benatar, "Towards Progress in Resolving Dilemmas," 575.

<sup>19</sup> Chirac and Torreele, "Global Framework on Essential Health R&D," 1560.

<sup>20</sup> Benatar, "Commentary: Justice and Medical Research," 337; Emanuel *et al*, "What Makes Clinical Research in Developing Countries Ethical?" 930. Ruth Macklin provides an illustrative example of how vulnerable groups have been exploited in biomedical research. She details the circumstances under which a large pharmaceutical company chose to trial a drug during a meningitis epidemic in an African country, including its failure to follow industry guidelines or informed consent procedures. (Macklin, "Bioethics, Vulnerability and Protection," 475-477.)

<sup>21</sup> Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries*, 4.

<sup>22</sup> Berlinguer, *op cit*, 1087.



addressing their health concerns than is currently the case.<sup>23</sup> Thus the challenge is to develop means by which ethical research in developing countries can continue and grow. Benatar and Singer have suggested as criteria that any proposed research should be relevant to the host country and likely to be of long-term benefit.<sup>24</sup> 'Benefit sharing' agreements may be one way to meet these criteria, by which funders and researchers commit to sharing any gains from scientific or technological research with participants or the wider community, whether directly in terms of profit or product or indirectly through capacity building and healthcare provision.<sup>25</sup> Berlinguer summarises the need for such measures as follows: "Benefit-sharing and equal access to advances in biomedical science are now urgent and *universal* issues"<sup>26</sup> (*italics added*).

### **2.1.2.3 Capacity for ethical review**

Ruth Macklin highlights the need for effective oversight of research: "If a country lacks a mechanism for identifying and sanctioning researchers who violate laws, regulations, or fundamental ethical standards in carrying out the research, then all research subjects are potentially vulnerable."<sup>27</sup> Benatar and Singer, in an article on the World Medical Association's *Declaration of Helsinki*, contend that building capacity in research ethics will have far more impact on ethical standards than "revisions of this or any other research ethics code."<sup>28</sup> Similarly, Bhutta argues that strengthening local capacity in bioethics is key to promoting ethical health research in developing countries.<sup>29</sup> Benatar also stresses the need for research to be effectively monitored once it has been approved.<sup>30</sup> Insufficient funding and training for RECs are often the biggest barriers to such endeavours, as identified by Nancy Kass *et al* in a recent study across several African countries (including

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<sup>23</sup> Macklin, *op cit*, 478.

<sup>24</sup> Benatar and Singer, "A New Look at International Research Ethics," 826.

<sup>25</sup> UNESCO, *Universal Declaration on Bioethics and Human Rights*, article 15.

<sup>26</sup> Berlinguer, *op cit*, 1088.

<sup>27</sup> Macklin, *op cit*, 475.

<sup>28</sup> Singer and Benatar, "Beyond Helsinki," 747.

<sup>29</sup> Bhutta, *op cit*, 117-118.

<sup>30</sup> Benatar, "Reflections and Recommendations," 1136 and 1137-1138.

Kenya and South Africa).<sup>31</sup> Capacity within RECs is not the only issue, however; both Sylvester Chima and Kass *et al* aver that committees need national level guidelines and policies to steer them, which do not always exist in developing countries.<sup>32</sup> In the context of genomics research, Dave Chokshi and Dominic Kwiatkowski link the need for local capacity with the need to contextualise universal principles: “Improving local capacity in bioethics in developing countries is essential to ensure that the philosophical principles of genomics ethics are informed by a practical understanding of what will work at the local level.”<sup>33</sup> With regard to developing capacity for research itself, as well as its review, Bhutta suggests that developing countries should be enabled to carry out research relevant to their needs. Petros Isaakidis *et al* assert that local researchers should play a substantial role in defining what these needs are, rather than have research priorities dictated to them by the North.<sup>34</sup>

### 2.1.3 Wider concerns

Debates in research ethics spill over from regulatory concerns to the broader issue of how inequalities of health between North and South should be addressed. Bhutta deems these “vital components of the same equation,”<sup>35</sup> as does Benatar:

Medical research, health care, conditions of life around the world and how humans flourish may seem separate, but they are all interdependent. Taking such a comprehensive global perspective adds complexity to the task of crafting universal research ethics guidelines.<sup>36</sup>

The “conditions of life” Benatar refers to include such basic needs as food, clean water and shelter, which have traditionally been considered outside the remit of bioethics.<sup>37</sup> As

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<sup>31</sup> Kass *et al*, “The Structure and Function of Research Ethics Committees in Africa,” 28.

<sup>32</sup> *Ibid*, 29; Chima, “Regulation of Biomedical Research in Africa,” 849.

<sup>33</sup> Chokshi and Kwiatkowski, “Ethical Challenges of Genomic Epidemiology in Developing Countries,” 12.

<sup>34</sup> Bhutta, *op cit*, 114; Isaakidis *et al*, “Relation Between Burden of Disease and Randomised Evidence in sub-Saharan Africa,” 4.

<sup>35</sup> Bhutta, *op cit*, 118.

<sup>36</sup> Benatar, “Justice and Medical Research,” 337.

<sup>37</sup> Turner, “Bioethics Needs to Rethink Its Agenda,” 175.



poverty is a direct factor in nearly one third of the worldwide disease load<sup>38</sup> (with disease also contributing to poverty, in a vicious circle), Benatar and Singer call for “a new, proactive research ethics” to address the global health inequities they see as being the greatest ethical challenge.<sup>39</sup> Several commentators, including Benatar and Singer, refer to the ‘10/90 gap’. This is a statistic that, although dating back to 1990, has become a kind of shorthand to describe disparities in healthcare: ninety per cent of the USD 56 billion spent annually on medical research is devoted to mitigating only ten per cent of the global disease burden.<sup>40</sup> Benatar frames global health in terms of a new concept of security that concentrates on improving life chances for everyone.<sup>41</sup> New infectious diseases have “shrunk distances and differences, and created common global risks.” The global nature of these risks, Benatar argues, means that it is in everyone’s “rational self-interest” to address them.<sup>42</sup> Harold Varmus, former director of the US National Institutes of Health, is of the same view. He calls for a “concerted effort to build health-related sciences in poor countries” as part of the solution.<sup>43</sup>

One way to promote the rational self-interest ethos may be through the concept of ‘global public goods’ (GPGs); that is, goods that are non-excludable (available to all) and non-rivalrous (consumption by one person does not prevent consumption by another), that can be found in the public domain and whose benefits are available worldwide. (Benatar attributes inequalities between rich and poor partly to under-attention to public goods.<sup>44</sup>) Inge Kaul and Michael Faust, of the United Nations Development Programme, see international cooperation on health as a GPG issue. Their rationale highlights the link between GPGs and self-interest: since national borders are porous to disease (and

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<sup>38</sup> Benatar, “Reflections and Recommendations,” 1132.

<sup>39</sup> Benatar and Singer, “A New Look at International Research Ethics,” 826.

<sup>40</sup> Benatar, “Justice and Medical Research,” 335 and Singer and Daar, “Harnessing Genomics and Biotechnology to Improve Global Health Equity,” 89; see also Benatar, “Reflections and Recommendations,” 1132 and 1138; Benatar, “Human Rights in the Biotechnology Era I”; Benatar and Singer, “A New Look at International Research Ethics,” 824; Singer and Benatar, “Beyond Helsinki,” 748; Berlinguer, *op cit*, 1088; Dowdeswell, Daar and Singer, “Bridging the Genomics Divide,” 3.

<sup>41</sup> About one fifth of research scientists and engineers work exclusively on military research and development. Benatar, “Global Disparities in Health and Human Rights,” 296.

<sup>42</sup> Benatar, “Bioethics: Power and Injustice,” 391.

<sup>43</sup> Varmus, “Building a Global Culture of Science,” s2.

<sup>44</sup> Benatar, “Moral Imagination,” 1208.



increasingly so as people travel more<sup>45</sup>), health conditions are globalised and thus “international cooperation in health has become a matter of self-interest and mutual concern.”<sup>46</sup> (Whether this is a viable use of the GPG concept is discussed more fully at 2.3.2.3.)

This section has introduced various principles that determine how research can be conducted ethically and how these might be applied in developing countries. It has also considered bioethics more broadly, in terms of the moral challenge of inequalities of health. The next section turns to genetics and genomics. It begins by outlining how these terms are understood. It then examines how ethical principles can be applied in the particular context of genetic and genomic research and how the outputs of this research might be harnessed to address the health concerns of the South.

## **2.2 GENETICS AND GENOMICS**

### **2.2.1 Background**

The term ‘genomics’ derives from the word ‘genome’. A genome is the sum total of all the DNA (deoxyribonucleic acid) in any given individual or organism.<sup>47</sup> DNA is made partly from four chemicals or bases, adenine, guanine, cytosine and thymine (abbreviated to A, G, C and T), which are sequenced in pairs along a genome. The human genome, for example, contains approximately three billion base pairs.<sup>48</sup> Genes are particular sequences of DNA within the genome that determine certain characteristics of an

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<sup>45</sup> Chen and Berlinguer, “Health Inequity in a Globalizing World,” 7.

<sup>46</sup> Kaul and Faust, “Global Public Goods and Health,” 869 and 870.

<sup>47</sup> WHO, *Genomics and World Health*, 4; US Department of Energy Office of Science, “What’s a Genome? And Why is it Important?” [www.ornl.gov/sci/techresources/Human\\_Genome/project/about.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml) (accessed 6 July 2007).

<sup>48</sup> US Department of Energy Office of Science, “What’s a Genome? And Why is it Important?”; Metcalfe, Hirst and Saunders, *An Introduction to the Human Genome*, 71.

organism, such as eye colour and contribute to others, such as health and behaviour.<sup>49</sup> Humans have approximately 99.9 per cent of their genome in common with each other, with differences in the remaining 0.1 per cent being responsible for genetic variation between individuals.<sup>50</sup> Estimates of the number of genes within the human genome range from 20 to 30 thousand;<sup>51</sup> whatever the number, genes account for only about three per cent of the genome's DNA. Some of the remaining DNA supports genes by, for example, activating them at the correct time, but much of it has no known function.<sup>52</sup>

Geneticists can determine the order in which base pairs appear in a genome through a process called DNA sequencing. The end result is a 'map' of where each gene is positioned, as well as the supporting and non-functioning DNA. The most famous example of DNA sequencing is the Human Genome Project, which published drafts and a completed version of the human genome sequence in 2000, 2003 and 2006 respectively.<sup>53</sup> Some are keen to draw a clear distinction between genomics and genetics (including those behind the GGI), as follows:

Genomics is the comprehensive examination of an organism's entire set of genes and their interactions (as distinct from genetics, which is the study of a single gene or a small number of genes to determine specific gene roles in diseases or physical characteristics of an individual).<sup>54</sup>

Since, however, a genome contains genes (as well as the other types of DNA) the terms are often used somewhat interchangeably. In 2004, for example, the World Health Assembly, the decision-making body of the World Health Organization (WHO), adopted by resolution WHA57.13 the following definition: "Genomics is the study of genes and their functions, and related techniques."<sup>55</sup> Similarly, the Human Genome Organisation (HUGO)

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<sup>49</sup> Metcalfe, Hirst and Saunders, op cit, 8.

<sup>50</sup> Schmidt, "Charting the Map of Life," A 26.

<sup>51</sup> US Department of Energy Office of Science, "How Many Genes Are in the Human Genome?" [www.ornl.gov/sci/techresources/Human\\_Genome/faq/genenumber.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/faq/genenumber.shtml) (accessed 6 July 2007).

<sup>52</sup> Metcalfe, Hirst and Saunders, op cit, 105-106.

<sup>53</sup> US Department of Energy Office of Science, "Facts About Genome Sequencing," [www.ornl.gov/sci/techresources/Human\\_Genome/faq/seqfacts.shtml#whose](http://www.ornl.gov/sci/techresources/Human_Genome/faq/seqfacts.shtml#whose) (accessed 6 July 2007).

<sup>54</sup> Smith, R *et al*, "Genomics Knowledge and Equity," 385. This definition appeared in a joint paper between scholars from the University of East Anglia, McGill University and the Toronto Joint Centre for Bioethics, which has proposed the GGI.

<sup>55</sup> WHO, "Fifty-Seventh World Assembly, Geneva, 17-22 May 2004: Resolutions and Decisions, Annexes," WHA57/2004/REC/1 (Geneva: 2004), 21.



describes itself as comprising “scientists involved in human genetics.”<sup>56</sup> Furthermore, in a separate paper to the one quoted above, those proposing the GGI define genomics very broadly, as “the powerful new wave of health-related life sciences energized by the human genome project and the knowledge and tools it is spawning.”<sup>57</sup> For the purposes of this thesis, ‘genetics’ will be used as a collective term for both genetics and genomics (the phrase “the governance of genetics and bioethics” is used frequently in the chapters that follow, for example). Hence the term ‘genomics’ appears only rarely, mainly in the context of the GGI.

### 2.2.2 Genetics In developing countries

Genetics has the potential to transform health and healthcare, in both developed and developing countries. As knowledge of both the nature and functions of the human genome increases, genetic influences on human disease patterns will be identified.<sup>58</sup> While the principal cause of many diseases may be environmental, a “growing body of molecular data” has led to the belief that there is a genetic component to almost all human diseases.<sup>59</sup> Kwiatkowski writes,

For example, genetic variation may partly explain why one child develops fatal cerebral malaria, or kwashiorkor, while other children living in the same compound are equally exposed to malaria parasites and to poor diet but do not develop these severe clinical syndromes. A huge amount of scientific effort is now being put into investigating the many different genetic factors that influence susceptibility to common diseases, in the hope that this will provide fundamental insights into molecular pathogenesis and ultimately lead to better methods of disease prevention.<sup>60</sup>

Infectious diseases such as malaria, HIV/AIDS and tuberculosis may involve several hundred genes, interacting both with each other and environmental risk factors. Genome-wide research enables the study of these complex diseases, affording valuable

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<sup>56</sup> HUGO, “Home,” [www.hugo-international.org/](http://www.hugo-international.org/) (accessed 4 July 2007).

<sup>57</sup> Acharya *et al*, *Genomics and Global Health*, xi.

<sup>58</sup> Giallourakis *et al*, “Disease Gene Discovery Through Integrative Genomics,” 399.

<sup>59</sup> Kwiatkowski, “Genetics,” 1.

<sup>60</sup> *Ibid*.



information concerning the molecular and cellular basis of disease in the search for effective vaccines and treatments.<sup>61</sup>

In 2002, WHO published a report entitled *Genomics and World Health*. The report, which received considerable attention worldwide,<sup>62</sup> states that “the science of genomics holds tremendous potential for improving health globally.” It advocates a holistic approach, stressing the importance of “fundamental overarching strategies to improve health,” such as poverty alleviation, health systems development and education, alongside genetic science.<sup>63</sup> Thus the value of any investment in genetics must be assessed relative to current approaches to healthcare and medical research, such that these more conventional mechanisms are not neglected.<sup>64</sup> The report also cautions that it will take time for the possible health benefits of genetic research to come to fruition and that, because these are likely to be expensive, they have the potential to increase disparities in health. This is all the more concerning because most developing countries “do not at present possess either the technological capacity or skill base to reap the potential benefits of genomics research and apply them to their health care needs.” Hence the report recommends that these developing countries should develop clinical genetic services, which would be the simplest means of building the necessary capacity, as they use well-established DNA technologies. They would also enable the control of diseases such as the common inherited haemoglobin disorders; sickle-cell anaemia affects 300,000 newborns in sub-Saharan Africa every year.<sup>65</sup>

Like WHO, the African Ministerial Council on Science and Technology (AMCOST) sees great potential in genetics (and the life sciences in general<sup>66</sup>) to fight diseases such as malaria and contribute to poverty reduction and economic growth. It has also similarly

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<sup>61</sup> Ibid, 2; Kwiatkowski, “Science, Medicine, and the Future,” 1062.

<sup>62</sup> The report generated commentaries in the journals *Science* and *Nature Genetics*. It was also announced in newspapers around the world, including *The New York Times*, *The Washington Post*, *The Toronto Star*, *Financial Times*, *Agence France Presse*, *New Straits Times* (Malaysia), *The Independent* (The Gambia) and *Africa News* (as revealed by a search of the database Nexis UK, 23 February 2007).

<sup>63</sup> WHO, *Genomics and World Health*, Foreword and 3.

<sup>64</sup> WHO, “Genomics and World Health: Report by the Secretariat,” 1-2.

<sup>65</sup> WHO, *Genomics and World Health*, Foreword, 6, 83, 187 and 189.

<sup>66</sup> That is, all branches of science that concern living organisms.

identified factors that could constrain the development potential of genetics and biotechnology, including insufficient scientific and technical capacity, infrastructure and funding. The Council aims to address these inadequacies through its 'flagship' research and development programme, Safe Development and Application of Biotechnology, by building a critical mass of scientific expertise, research facilities and financial resources.<sup>67</sup> In August 2007, a High-Level African Panel on Modern Biotechnology (set up, like AMCOST, under the auspices of the African Union and NEPAD, the New Partnership for Africa's Development), produced a report on biotechnology in Africa. The report recommends that each African region should implement "long-term 'biotechnology missions'" around particular themes; with southern Africa to host a health biotechnology cluster.<sup>68</sup>

### **2.2.3 Why genetics needs governance**

Human genetic research, like biomedical research in general, stretches beyond national borders:

An orders-of-magnitude increase in scale of genetic data collection has created the need for establishing diffuse international partnerships, sometimes across developed- and developing-world countries, with ramifications for assigning research ownership, distributing intellectual property rights, and encouraging capacity-building.<sup>69</sup>

While genetics holds great promise, then, it also carries new ethical dilemmas, concerning both individuals and communities, which require international governance. Governance at national level is also an issue. The WHO report *Genomics and World Health* found that

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<sup>67</sup> NEPAD, "Flagship R&D Programmes," [www.nepadst.org/platforms/biotech.shtml](http://www.nepadst.org/platforms/biotech.shtml) (accessed 20 June 2007). AMCOST was established in November 2003 to coordinate and implement the science and technology programmes of NEPAD (the New Partnership for Africa's Development) and the African Union, under "Africa's Science and Technology Consolidated Plan of Action," which can be downloaded at [www.nepadst.org/doclibrary/pdfs/ast\\_plan\\_of\\_action.pdf](http://www.nepadst.org/doclibrary/pdfs/ast_plan_of_action.pdf) (accessed 25 June 2007).

<sup>68</sup> High-Level African Panel on Modern Biotechnology, *Freedom to Innovate*, iii and xvii.

<sup>69</sup> Chokshi and Kwiatkowski, op cit, 1.



many developing countries do not have regulatory, ethical or policy frameworks in place to deal with genetics.<sup>70</sup>

### **2.2.3.1 Concerns for individual rights**

One general concern in genetics is to balance freedom of research with individual rights.

AM Duguet expresses this concern thus:

An acknowledged principle in our democratic societies, freedom in research, is viewed as inherent to freedom of thinking and it is therefore accepted that its finalities be unrestricted. However, genetic research explores a very sensible domain. Indeed, what is under investigation is a person's intimate inheritance, origins, future and progeny.<sup>71</sup>

Fears of discrimination on the basis of the information their genome contains may render some people reluctant to participate in genetic research. Thus confidentiality must be protected.<sup>72</sup> A complicating factor is that, while each person's genome is unique, it also carries information about their families (and possibly communities).<sup>73</sup> This has consequences for how far someone's right to autonomy should allow them to control personal genetic information.<sup>74</sup> Other issues requiring guidance include the transfer of samples and data across national borders, particularly given the increase in international research projects. Standardisation of procedures would enable both better protection of individual rights and further transnational research cooperation.<sup>75</sup>

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<sup>70</sup> WHO, *Genomics and World Health*, 187-188.

<sup>71</sup> Duguet, "Genetic Research," 203.

<sup>72</sup> Reilly, "Public Concern About Genetics," 489; Anderlik and Rothstein, "Privacy and Confidentiality of Genetic Information" 404 and 405.

<sup>73</sup> Knoppers, "Genetic Information and the Family," 86.

<sup>74</sup> Laurie, "Challenging Medical-Legal Norms," 1.

<sup>75</sup> Godard *et al*, "Data Storage and DNA Banking for Biomedical Research," S104.



### 2.2.3.2 *Benefit sharing*

Chokshi and Kwiatkowski capture a major dilemma in genetic research with the question, “What is the structure of an equitable and fair system for distributing the financial and scientific rewards of research?”<sup>76</sup> Some scientists are concerned that the patenting of gene sequences, including human ones, could be detrimental to both scientific advancement and healthcare provision.<sup>77</sup> Researchers may be reluctant to share findings for fear of precluding possible patents, while the cost of licence fees for gene-based products could render some treatments unaffordable. Others argue that, without the legal protection of intellectual property, there will be little incentive for companies to invest in research.<sup>78</sup> The human genome itself is in the public domain, but data on the products derived from the information therein may not be. Richard Dahl writes, “The mapping of the human genome opens huge potential markets for pharmaceutical and biotechnologic product developments, which take time and money. The question is, how much patent protection should those efforts enjoy?”<sup>79</sup>

Some are concerned with the idea of gene sequencing at a more fundamental level. Eike-Henner Kluge argues that the patenting of human genes is “ethically indefensible and amounts to an unjustified appropriation of a general human heritage.”<sup>80</sup> The characterisation of the human genome as the “common heritage of humanity”<sup>81</sup> promotes the idea of benefit sharing.<sup>82</sup> Who exactly deserves to benefit is complicated, however, given that several parties will have contributed to the process of deriving a gene-based health product, from those who have given genetic samples through to those who take it

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<sup>76</sup> Chokshi and Kwiatkowski, *op cit*, 1.

<sup>77</sup> Andrews, “Genes and Patent Policy,” 803.

<sup>78</sup> Schmidt, *op cit*, A 29.

<sup>79</sup> Dahl, “Pending Resolution,” A 32.

<sup>80</sup> Kluge, “Patenting Human Genes,” *Health Care Analysis*, 119.

<sup>81</sup> HUGO Ethics Committee, *Statement on Human Genomic Databases*.

<sup>82</sup> Knoppers and Chadwick, “Human Genetic Research,” 77.

to market.<sup>83</sup> Using a similar rationale to Benatar's self-interest argument, Chokshi and Kwiatkowski advocate a broad approach to benefit sharing in genetics:

If we assert first that the reference human genome sequence belongs to mankind and second that, given the positive-externality effects of vaccines and therapies for infectious diseases, research is of potential benefit to all, it follows that the aims of benefit-sharing should shift from purely local interests to broader interests.<sup>84</sup>

Sections 2.1 and 2.2 have outlined some of the dilemmas and issues in bioethics and genetics, particularly those concerning developing countries. Section 2.3 introduces two governance mechanisms that might provide means to address these issues.

## **2.3 THE UNESCO DECLARATIONS AND THE GLOBAL GENOMICS INITIATIVE**

### **2.3.1 Contrasting mechanisms**

UNESCO is a long-standing agency of the United Nations (UN), comprising 192 member states. It was founded in 1945, aiming to “build peace in the minds of men” through education, science, culture and communication.<sup>85</sup> It attempts to fulfil this aim through various activities and programmes, including the adoption and implementation of international declarations on genetics and bioethics. The Joint Centre for Bioethics at the University of Toronto sees such organisations as “unwieldy, sometimes inflexible, and largely inadequate.” It thus suggests what it believes will be a faster, more efficient alternative: the Global Genomics Initiative.<sup>86</sup>

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<sup>83</sup> Chokshi and Kwiatkowski, *op cit*, 10-11. Chokshi and Kwiatkowski give the following example: “It is... unclear who deserves to gain financially from, for instance, the discovery of a novel anti-malarial molecule from studies of national genetic diversity. Any of at least five groups can make a claim: the subjects themselves, the health professionals who diagnosed and treated them, the epidemiologists who managed the study, the geneticists who produced the result, and the company that makes the end product. As Chadwick and Berg have pointed out, while our moral intuitions may sympathize most with the subjects' claim, it is the scientists who have actually made the subjects' samples 'valuable.'”

<sup>84</sup> *Ibid*, 11.

<sup>85</sup> UNESCO, “What is it? What does it do? About UNESCO,” [http://portal.unesco.org/en/ev.php-URL\\_ID=3328&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=3328&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 22 June 2007).

<sup>86</sup> Acharya *et al*, “Better Global Governance to Promote Genomics for Development,” 4-5.



### 2.3.1.1 Background to the UNESCO declarations

In recent years UNESCO has produced a series of declarations on genetics and bioethics: the 1997 *Universal Declaration on the Human Genome and Human Rights*, the 2003 *International Declaration on Human Genetic Data* and the 2005 *Universal Declaration on Bioethics and Human Rights*. The three declarations are to be treated integrally and indeed there is much common ground between them.<sup>87</sup> As a set, they prescribe how human genetic and biomedical research can be conducted ethically and encourage capacity building and knowledge sharing in science and ethics, particularly between North and South.

According to its website, UNESCO actively pursues the Millennium Development Goals<sup>88</sup> and “functions as a laboratory of ideas and a standard-setter to forge universal agreements on emerging ethical issues.”<sup>89</sup> It has a mandate to advise member states on developing national capacities.<sup>90</sup> The ethics of science and technology (and particularly bioethics) is a priority within Social and Human Sciences, one of UNESCO's five specialised sectors.<sup>91</sup> UNESCO aims to consolidate the universal values of justice, freedom and dignity, while acknowledging pluralism: “Scientific and technological progress must be placed in a context of ethical reflection rooted in the cultural, legal, philosophical and religious heritage of all our communities.”<sup>92</sup>

The UNESCO Bioethics Programme, part of the Division of the Ethics of Science and Technology, began in 1993 with the formation of the International Bioethics Committee

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<sup>87</sup> UNESCO, “Address by Mr Koïchiro Matsuura, Director General of UNESCO,” twelfth session of the IBC, Tokyo, Japan, 15-17 December 2005, DG/2005/201, 3.

<sup>88</sup> The Millennium Development Goals are an initiative of the UN. The eight goals cover issues such as education, health and poverty and have a target date of 2015. For more information see [www.un.org/millenniumgoals/](http://www.un.org/millenniumgoals/).

<sup>89</sup> UNESCO, “What is it? What does it do? About UNESCO.”

<sup>90</sup> UNESCO, “Social and Human Sciences,” [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=1830&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=1830&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 22 June 2007).

<sup>91</sup> UNESCO, “Major Fields of Action and Priorities,” [http://portal.unesco.org/en/ev.php-URL\\_ID=6406&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=6406&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 22 June 2007).

<sup>92</sup> UNESCO, “Social and Human Sciences.”



(IBC). An Intergovernmental Bioethics Committee (IGBC) followed in 1999.<sup>93</sup> Each committee has 36 members, the former made up of independent experts and the latter of representatives from selected member states (see 5.1.1.1 and 5.1.2.1 for more details).<sup>94</sup> Beyond UNESCO Headquarters in Paris, many of UNESCO's activities are administered through the National Commissions in each member state.<sup>95</sup> UNESCO also provides the secretariat for the UN Inter-Agency Committee on Bioethics, established in 2001.<sup>96</sup>

### **2.3.1.2 Background to the Global Genomics Initiative**

In parallel to the UNESCO declarations, a second international initiative around genetics and bioethics has been proposed. Academics at the Toronto Joint Centre for Bioethics (TJCB) have laid out plans for a global network, the Global Genomics Initiative (GGI). The network would have a multisectoral membership, with leadership from the South. Among other activities, it would (like UNESCO) design norms for the ethical governance of genomic research and encourage capacity building and knowledge sharing.<sup>97</sup>

Although TJCB has suggested this initiative partly because it views more traditional international organisations as ineffective, some of its members are closely connected with UN-based institutions. Firstly, Peter Singer and Abdallah Daar, who direct the McLaughlin-Rotman Centre for Global Health (the mission of which is to “harness the advances of

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<sup>93</sup> UNESCO, “Bioethics,” [www.unesco.org/bioethics](http://www.unesco.org/bioethics) (accessed 7 October 2004); UNESCO, “International Bioethics Committee (IBC),” [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=1879&URL\\_DO=DO\\_PRINTPAGE&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=1879&URL_DO=DO_PRINTPAGE&URL_SECTION=201.html) (accessed 7 October 2004); UNESCO, “First Session of the Intergovernmental Bioethics Committee (IGBC),” [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=7062&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=7062&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 18 July 2005). The first Committee was elected by the Executive Board in 1998, but did not meet until October 1999. (UNESCO, “Decisions Adopted by the Executive Board at its 155th Session,” 155 EX/Decisions, Paris, 3 December 1998, 67.)

<sup>94</sup> UNESCO, “Bioethics,” [www.unesco.org/bioethics](http://www.unesco.org/bioethics) (accessed 22 June 2007). When first established in 1993, the IBC had around fifty members. It was reconstituted in 1998, when the limit of 36 members was specified in its statutes. (UNESCO, *Birth of the Universal Declaration on the Human Genome and Human Rights*, 1; Andorno, “Seeking Common Ground on Genetic Issues,” 120.)

<sup>95</sup> UNESCO, “Social and Human Sciences: Guide to Partnerships,” 6.

<sup>96</sup> UNESCO, “Ethics,” [www.unesco.org/ethics](http://www.unesco.org/ethics) (accessed 22 June 2007).

<sup>97</sup> The GGI would be concerned with both human and non-human genomics, as well as other forms of biotechnology that fall under biomedicine and thus are analogous to the types of research and technology covered by UNESCO's *Universal Declaration on Bioethics and Human Rights*.

innovative technology for global health equity<sup>98</sup>) within TJCB, are special advisors to the WHO Genomics Resource Centre. Secondly, the Genomics and Nanotechnology Working Group of the Science, Technology and Innovation Task Force of the UN Millennium Project (Task Force 10) was comprised entirely of members of TJCB (and suggested the GGI as a means to achieve the Millennium Development Goals in its report *Genomics and Global Health*).<sup>99</sup> Abdallah Daar also sat on the High-Level African Panel on Modern Biotechnology and was a member of the HUGO Ethics Committee when it drafted its 2002 statement on human genetic databases.<sup>100</sup>

### **2.3.2 Why the mechanisms are deemed necessary**

Just as the two mechanisms have contrasting backgrounds, so do their proponents give contrasting rationales for why they are necessary. Whereas TJCB has proposed the GGI because of what it perceives to be the failure of existing governance systems to act with sufficient urgency to harness the potential of genomics, UNESCO justifies its activities in genetics and bioethics precisely on the grounds that these require governance at the intergovernmental level.

#### **2.3.2.1 UNESCO's rationale**

As explained above, one of UNESCO's key activities is the setting of international standards, which member states can subsequently draw on to establish regulatory or legal frameworks at national level. Koïchiro Matsuura, Director-General of UNESCO, expresses

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<sup>98</sup> The Centre was formerly the Canadian Program on Genomics and Global Health. It is financed by a diverse range of actors, including WHO, the Grand Challenges in Global Health initiative, Canadian governmental programmes, private foundations and universities. (McLaughlin-Rotman Centre for Global Health, "Welcome to Our Site," [www.utoronto.ca/jcb/genomics/index.html](http://www.utoronto.ca/jcb/genomics/index.html), accessed 20 June 2007 and "Funding," [www.utoronto.ca/jcb/genomics/html/funding.htm](http://www.utoronto.ca/jcb/genomics/html/funding.htm), accessed 3 July 2007.)

<sup>99</sup> UN Millennium Project 2005, *Innovation: Applying Knowledge in Development*, xii and xix; Acharya *et al*, *Genomics and Global Health*, viii, xi-xii and 43.

<sup>100</sup> High-Level African Panel on Modern Biotechnology, *op cit*, vii; HUGO Ethics Committee, *op cit*.



the need for standards within science and technology in terms of transnational practices and benefit sharing:

Present-day scientific practices cross national borders. Hence the imperative need to take action together at the international level—not to erect barriers against these practices, but to provide the necessary oversight so that the benefits of science may be enjoyed by all humanity...<sup>101</sup>

UNESCO sees itself as particularly well-suited to standard-setting in bioethics, as the only UN organisation with competencies in both human and social sciences. As science and technology advances, its “ethical watch mandate” becomes more and more pertinent.<sup>102</sup> Publications, speech transcripts and the UNESCO website all emphasise its unique or leading role in this field.<sup>103</sup> Roberto Andorno, a former member of the IBC, additionally argues that international organisations such as UNESCO provide the “ideal arena” for the discovery of universal norms, because they enable open dialogue between representatives of different cultural traditions and values.<sup>104</sup> (How far this is in fact the case will be assessed in Chapter 5.)

UNESCO’s intergovernmental status is a key factor in its justification for its bioethics activities. After the *Universal Declaration on the Human Genome and Human Rights* (UDHGHR) was endorsed by the United Nations General Assembly in 1998, for example, it was described as “the only international instrument in the field of bioethics.”<sup>105</sup> This would imply that bioethics guidelines produced by other organisations, such as the World Medical Association and the Council for International Organizations of Medical Sciences, are not truly ‘inter-national’, because they have not been agreed by nation-states. (To

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<sup>101</sup> UNESCO, “Social and Human Sciences: Strategies and Actions,” 10 and 13.

<sup>102</sup> UNESCO, “Bioethics,” [www.unesco.org/bioethics](http://www.unesco.org/bioethics) (accessed 7 October 2004).

<sup>103</sup> UNESCO, “Towards a Declaration on Universal Norms on Bioethics,”

[http://portal.unesco.org/shs/en/ev.php-URL\\_ID=1883&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=1883&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 7 October 2004). See also: UNESCO, “Bioethics,” [www.unesco.org/bioethics](http://www.unesco.org/bioethics) (accessed 22 June 2007); UNESCO, “Bioethics: International Implications,” 1; UNESCO, “Address by Mr Koïchiro Matsuura, Director General of UNESCO,” twelfth session of the IBC, 4; UNESCO, “Report of the Second Session of the Intergovernmental Bioethics Committee (IGBC),” 1; UNESCO, “Report by the Director-General on the Work of the IBC and of the IGBC,” 1 and 5; UNESCO, “Social and Human Sciences: Strategies and Actions,” 10 and 13.

<sup>104</sup> Andorno, “Biomedicine and International Human Rights Law,” 959.

<sup>105</sup> UNESCO, “Bioethics,” [www.unesco.org/bioethics](http://www.unesco.org/bioethics) (accessed 22 June 2007).



what extent the declarations' intergovernmental origins confer authority will be discussed further in Chapters 5 and 6.)

The UDHGHR (1997) was adopted in order to facilitate a balance between progress in genetics and protection of human rights. The Preamble states:

The General Conference,... recognizing that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but emphasizing that such research should fully respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics, proclaims the principles that follow and adopts the present Declaration.<sup>106</sup>

Although the declaration covers human genetic data in a general sense, it was felt that their collection, processing, storage and use needed to be addressed more specifically. Growth in the number of human genetic databases and international research programmes, increasing private sector involvement and the need to protect vulnerable populations were all contributing factors to this decision.<sup>107</sup> UNESCO duly adopted the *International Declaration on Human Genetic Data* (IDHGD) in 2003, as “an extension and means of implementing” the UDHGHR (1997).<sup>108</sup>

While the negotiations for the IDHGD were still ongoing, UNESCO was already looking towards a third bioethics instrument, one that would address the field as a whole rather than genetics specifically. This was considered necessary because “a growing number of scientific practices have extended beyond national borders.”<sup>109</sup> The UNESCO website defines bioethics as follows:

Stem cell research, genetic testing, cloning: progress in the life sciences is giving human beings new power to improve our health and control the development processes of all living species. Concerns about the social, cultural, legal and ethical implications of such progress have led to one of the most significant debates of the past century. A new word has been coined to encompass these concerns: bioethics.<sup>110</sup>

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<sup>106</sup> UNESCO, *Universal Declaration on the Human Genome and Human Rights*, Preamble.

<sup>107</sup> UNESCO, “Human Genetic Data: Preliminary Study of the IBC,” 2 and 3.

<sup>108</sup> UNESCO, “Meeting of Government Experts Responsible for Finalizing the Draft International Declaration on Human Genetic Data: Final Report,” 1.

<sup>109</sup> UNESCO, “Towards a Declaration on Universal Norms on Bioethics.”

<sup>110</sup> UNESCO, “Bioethics,” [www.unesco.org/bioethics](http://www.unesco.org/bioethics) (accessed 22 June 2007).

That bioethics, under this definition, extends beyond medical ethics and thus beyond existing professional codes of ethics (such as the World Medical Association's *Declaration of Helsinki*) was one of the reasons given by UNESCO for the elaboration of the *Universal Declaration on Bioethics and Human Rights* (UDBHR), adopted late in 2005. It was decided that universal guidelines on "all issues" in bioethics were needed.<sup>111</sup> The text contains no reference to issues such as stem cells, however, because they proved too controversial to enable consensus between member states. Thus the original aim proved over-ambitious. Illustrating a complete reversal, a 2005 report describes the IBC's final draft text as "far from attempting to resolve all the existing bioethics issues."<sup>112</sup>

Where the declaration does encompass a broad understanding of what should be considered as bioethics is in regard to social and environmental issues. These were considered important elements of the proposed declaration from an early stage. The 2003 "Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics" reads: "Our global society must face the responsibility to use science and technology to promote public health and to equalize access to healthcare and medicines" (Berlinguer was rapporteur to the working group that compiled the report).<sup>113</sup> Henk ten Have, Head of UNESCO's Division of the Ethics of Science and Technology, explains, "Research into stem cells and cloning does not for now affect the lives of most people. They remain a hope for the future, but right now, people are dying because of poor health conditions. We must concentrate on this problem."<sup>114</sup>

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<sup>111</sup> UNESCO, "Towards a Declaration on Universal Norms on Bioethics."

<sup>112</sup> UNESCO, "Report by the Director-General on the Drawing Up of a Declaration on Universal Norms for Bioethics," 7.

<sup>113</sup> UNESCO, "Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics," 4 and Annex.

<sup>114</sup> Samir Tounsi, "Giving Science a Conscience," [http://portal.unesco.org/unesco/ev.php?URL\\_ID=30524&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=20](http://portal.unesco.org/unesco/ev.php?URL_ID=30524&URL_DO=DO_TOPIC&URL_SECTION=20) (accessed 25 May 2007).



### 2.3.2.2 TJCB's rationale

Academics at TJCB frame the likely increase in disparities in health between North and South during the biotechnology era (as predicted by the WHO *Genomics and World Health* report) as a potential “genomics divide.”<sup>115</sup> Like AMCOST, they argue that lack of investment, infrastructure and expertise is constraining the ability of developing countries to capitalise on the promise of genomics. TJCB sees genomics as a global public good (see below), because it is represented by knowledge in the public domain and across national boundaries. Where countries are excluded from using publicly available genomic knowledge to address their health needs by lack of scientific capacity, it becomes in essence a ‘club good’ (see below).<sup>116</sup> The failure to use genomics to combat health inequities is why TJCB deems governance at the global level necessary: “The global public-goods lens magnifies the failures of the global community to realise the full potential of genomics, and shines a light on needed collective actions to harness genomics to improve global health-equity.”<sup>117</sup>

TJCB describes the promotion of genomics as “all-important” to global health equity.<sup>118</sup> Temidayo Ogundiran, in an article entitled “Africa Must Come on Board the Genomics Bandwagon,” agrees. He sees genomics as a potential tool to narrow health inequalities, one that might “hold the ace for improving the standards of living of the African people” (although he describes the continent as occupying the “spectator’s seat” at present).<sup>119</sup> There is a contested viewpoint. Benatar, who with Daar and Singer has called for global action on inequalities of health, is sceptical of genetics as the way forward. He questions whether biotechnology will really help the poor, if drugs that have already been developed

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<sup>115</sup> Singer and Daar, *op cit*, 87. It is interesting to note that in early discussions on the possibility of elaborating an international instrument on bioethics UNESCO also referred to a genomics divide (without explicitly using the term). Part of a 2001 resolution of the UNESCO Executive Board reads, “Recognizing the supreme importance of preventing the widening of the international divide as a result of the latest technological revolution in the field of the human genome and affirming UNESCO’s crucial role in building global solidarity for this purpose...” (UNESCO, “Bioethics Programme,” 31 C/55, 1.)

<sup>116</sup> Acharya *et al*, “Better Global Governance to Promote Genomics for Development,” 3; Smith, R *et al*, *op cit*, 386 and 387.

<sup>117</sup> Thorsteinsdóttir *et al*, “Genomics—A Global Public Good?” 892.

<sup>118</sup> Dowdeswell *et al*, “Realising the Promise of Genomics,” 134.

<sup>119</sup> Ogundiran, “Africa Must Come on Board the Genomics Bandwagon,” 66 and 67. Ogundiran cites Daar and Singer in making his argument.



for diseases such as malaria, tuberculosis and HIV/AIDS have not been made available to the very many people in the South that need them.<sup>120</sup> With Gopal Sreenivasan, he advocates a more holistic approach, predicting that scientific advances in biotechnology will have little impact if broad disparities in wealth and health are not addressed with equal enthusiasm.<sup>121</sup>

TJCB hopes to ensure that genomics succeeds where other biomedical advances have failed through setting up a new governance framework for its promotion and management. As it sees traditional international organisations as ill-equipped to deal with urgent and rapidly changing issues such as genomics, this framework will have to take on an innovative form.<sup>122</sup> The several evolutionary stages the plans have gone through since the idea was first mooted in 2001 are chronicled in 2.3.3.

### ***2.3.2.3 Global public goods***

The 'global public goods' concept is a contested one. It is therefore necessary to explicate the context in which it is applied by TJCB and how it is used in this thesis. The term 'public good' originated in economics, where it has a precise meaning: non-rivalrous and non-excludable.<sup>123</sup> A global public good (GPG) is a public good with cross-border benefits on a global level. Where public goods are often supplied by governments because their non-rivalrous and non-excludable natures subject them to market failure, the issue for GPGs becomes how they can be supplied in the absence of a global government.<sup>124</sup> Private goods ('access goods') may be required to enable access to some public goods. Non-rivalrous but excludable goods are called 'club goods'.<sup>125</sup>

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<sup>120</sup> Benatar, "Human Rights in the Biotechnology Era I."

<sup>121</sup> Sreenivasan and Benatar, "Challenges for Global Health in the 21<sup>st</sup> Century," 3. See also Benatar, "Bioethics: Power and Injustice," 397.

<sup>122</sup> Acharya *et al*, "Better Global Governance to Promote Genomics for Development," 1.

<sup>123</sup> Robson, "A 'Public Good' is Not Just Something Which is 'Good for the Public'," 39.

<sup>124</sup> Smith, "Global Public Goods and Health," 475.

<sup>125</sup> Smith and MacKellar, "Global Public Goods and the Global Health Agenda."

The broader GPG literature appears to understand the word 'good' in two ways: firstly, in the economic sense of a good or service (that is, a material or non-material product); secondly, as denoting an intrinsic quality. The United Nations Development Programme (UNDP) has sponsored two studies on GPGs (published in 1999 and 2003 and both co-edited by Inge Kaul). The second of these describes public goods as "the public's goods—goods that are in the public domain and may concern all people."<sup>126</sup> It develops a two-level classification, distinguishing between a good's potential for 'publicness' and its *de facto* non-exclusivity and availability and thus highlighting that whether or not a good is public can depend on policy choice or technological capacity.<sup>127</sup> A further book on GPGs was also published in 2003, entitled *Global Public Goods for Health*, in which David Woodward and Richard Smith offer a functional definition: "A good which it is rational, from the perspective of a group of nations collectively, to produce for universal consumption, and for which it is irrational to exclude an individual nation from consuming, irrespective of whether that nation contributes to its financing."<sup>128</sup> Wherein lies the contestation over the GPG concept is whether it should be understood broadly or as per its original economic formulation. UNDP's intention was to introduce public goods to a wider audience as a policy tool,<sup>129</sup> but some believe this has weakened the utility of the concept.<sup>130</sup> Economist Alex Robson laments the "abuse" of the term in public debate and, in direct contrast to UNDP, states, "The fact that something is consumed by many people and provides each of them with significant benefits does not make it a public good."<sup>131</sup>

There are two aspects to genomics as a GPG. Firstly, much genetic information is in the public domain and hence is non-excludable and non-rivalrous for those who have the means to access it. Secondly, more normatively, it could be argued that nobody should be

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<sup>126</sup> Kaul *et al*, "Why Do Global Public Goods Matter Today?" 14.

<sup>127</sup> Kaul *et al*, "How to Improve the Provision of Global Public Goods," 23.

<sup>128</sup> Woodward and Smith, "Global Public Goods for Health," 9, quoted in Smith and MacKellar, "Global Public Goods and the Global Health Agenda."

<sup>129</sup> Kaul *et al*, "Why Do Global Public Goods Matter Today?" 6.

<sup>130</sup> Richard Smith and Landis MacKellar, for example, argue that "GPG" is in danger of becoming a label for anything promoting development. (Smith and MacKellar, *op cit.*) Maurizio Carbone reviews opinions on GPGs in his paper "Supporting or Resisting Global Public Goods? The Policy Dimension of a Contested Concept" (185). He notes that several scholars have questioned the fusing of four diverse theories—public and private goods, positive and negative externalities, basic needs and collective goods—into one catch-all concept.

<sup>131</sup> Robson, *op cit*, 40.



excluded from benefits arising from the use of the human genome sequence, because it is the 'heritage of humanity'. TJCB is concerned with how the GPG characteristics of genomic knowledge can be harnessed to help address the health needs of developing countries, through research capacity building and the provision of access goods, for example. It foresees that collective action on an international scale will be necessary to achieve this and has thus proposed the GGI.<sup>132</sup> With regard to genetics, this is also the context in which the GPG concept is understood in this thesis; that is, in terms of what might be an effective governance mechanism to ensure developing countries are able to take advantage of genetic data in the public domain. Related concepts of rational self-interest and benefit sharing are also considered.

### **2.3.3 History of the two mechanisms**

#### **2.3.3.1 *The UNESCO declarations***

In 1993, the then Director-General of UNESCO, Federico Mayor, decided that the organisation should set up an International Bioethics Committee (IBC), so that it "could play its full role in the world of the future." The Committee's first task was to prepare an international instrument on the human genome (the eventual UDHGHR). It appointed a Legal Commission to propose what form and substance the instrument should take, which met regularly between April 1994 and December 1996. An international consultation was launched in May 1995. After receiving a progress report in November 1995, the twenty-eighth UNESCO General Conference requested that a draft declaration be developed, to be finalised by a committee of government experts appointed by member states (as per established protocol within the UN). The resultant draft was adopted "unanimously and by

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<sup>132</sup> Thorsteinsdóttir *et al*, *op cit*, 892.



acclamation” at the twenty-ninth General Conference, in November 1997. A year later the UDHGHR was endorsed by the United Nations General Assembly.<sup>133</sup>

As alluded to previously, UNESCO felt that rapid developments in the field of human genetic data required urgent and specific action.<sup>134</sup> The IBC had already produced two reports on this subject when the Director-General of UNESCO requested in May 2001 that it look into drafting an international instrument thereupon.<sup>135</sup> The thirty-first General Conference endorsed the initiative the following November and the IBC duly set up a drafting group. After widespread written and verbal consultations and further scrutiny by the IBC, the Executive Board,<sup>136</sup> an intergovernmental meeting of experts and a working group, the draft IDHGD was adopted “unanimously and by acclamation” on 16 October 2003, at the thirty-second General Conference.<sup>137</sup>

In 2001 the General Conference had invited the Director-General to look into the possibility of elaborating a universal instrument on bioethics.<sup>138</sup> On the basis of the IBC’s subsequent report, the 2003 General Conference declared the setting of universal standards in bioethics to be “imperative and desirable.”<sup>139</sup> The drafting process for the UDBHR was launched in January 2004.<sup>140</sup> As with the previous two declarations, a drafting group was appointed and an extensive consultation process initiated, involving member states and other stakeholders. The outline text of the declaration was also

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<sup>133</sup> UNESCO *Birth of the Universal Declaration on the Human Genome and Human Rights*, IV, 1-2 and 67.

<sup>134</sup> UNESCO, “UNESCO Adopts International Declaration on Human Genetic Data,” [http://portal.unesco.org/en/ev.php-URL\\_ID=16742&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=16742&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 21 June 2007).

<sup>135</sup> See UNESCO, “Report on Confidentiality and Genetic Data,” BIO-503/99/CIB-6/GT-2/3 (Paris: 30 June 2000) and “Human Genetic Data: Preliminary Study of the IBC.”

<sup>136</sup> The Executive Board is elected by the biennial General Conference and constitutes 58 member states. Its mandate is to ensure the effective and rational execution of the organisation’s programme of work. (UNESCO, “UNESCO’s Executive Board,” [http://portal.unesco.org/en/ev.php-URL\\_ID=25566&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=25566&URL_DO=DO_TOPIC&URL_SECTION=201.html), accessed 23 November 2007.)

<sup>137</sup> UNESCO, “International Declaration on Human Genetic Data,” [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=1882&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=1882&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 21 June 2007); UNESCO, “Meeting of Government Experts: Final Report,” 3. Fifty-seven member states, among which Kenya and South Africa did not feature, took part in the intergovernmental meeting of experts. (Ibid, 1.)

<sup>138</sup> UNESCO, “Towards a Declaration on Universal Norms on Bioethics.”

<sup>139</sup> UNESCO, “Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics,” 10; Berlinguer, op cit, 1088.

<sup>140</sup> UNESCO, “Towards a Declaration on Universal Norms on Bioethics: Progress Report January 2005,” PowerPoint presentation available at [http://portal.unesco.org/shs/en/file\\_download.php/50523d754289e00aad6d16990d576e22Bioethics+Declarati on\(jan.2005\).ppt](http://portal.unesco.org/shs/en/file_download.php/50523d754289e00aad6d16990d576e22Bioethics+Declarati on(jan.2005).ppt) (accessed 9 July 2007).

discussed by the IBC and IGBC, the Executive Board and the UN Inter-Agency Committee on Bioethics. The draft was finalised by two meetings of government experts in April and June 2005 and, like its predecessors, adopted “by acclamation” by the General Conference, on 19 October 2005 at its thirty-third session.<sup>141</sup>

### **2.3.3.2 The Global Genomics Initiative**

The roots of the GGI go back to 2001, when Daar and Singer, writing in *Science*, suggested that a commission on genomics and global health might aggregate stakeholders and raise awareness and resources to fight health inequalities.<sup>142</sup> Two years later, with Elizabeth Dowdeswell, they made a similar recommendation in the journal *Global Governance*:

An appropriate response by the world community—governments, citizens, and experts from industry and academia—would be to foster global dialogue and provide a forum for shaping the necessary governance framework through a commission on genomics and global health.<sup>143</sup>

By 2004 the vision had progressed. A paper produced by TJCB entitled “Better Global Governance to Promote Genomics for Development” put forward a model for a “new global network for governance,” as a means to balance the risks and benefits of genomics.<sup>144</sup> The initial plans for this network, published in both “Better Global Governance” and the Task Force 10 report *Genomics and Global Health*, followed Jean-François Rischard’s ‘global issues networks’ model (see Chapter 3), with its membership

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<sup>141</sup> UNESCO, “Different Stages in the Elaboration of the Declaration on Universal Norms on Bioethics,” [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=3850&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=3850&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 9 July 2007); UNESCO, “Towards a Declaration on Universal Norms on Bioethics,” PowerPoint presentation. The declaration was also discussed at an international conference in February 2005 in Paris. This was organised by the French National Commission for UNESCO and an external organisation, the International Association for Law, Ethics and Science and thus was not officially part of the elaboration process. (“Bioethics & International Law: Programme,” 25-26 February 2005.)

<sup>142</sup> Singer and Daar, op cit, 89.

<sup>143</sup> Dowdeswell, Daar and Singer, op cit, 1.

<sup>144</sup> Acharya et al, “Better Global Governance to Promote Genomics for Development,” 1, 2 and 4. Note, however, that many of the stipulations for the network, such as the need for urgency, creative thinking, new financial models and champions from government, industry and civil society, remained the same as for the commission. (Ibid, 6-7; Dowdeswell, Daar and Singer, op cit, 5-6.)



to include representatives from governments, industry, academia, non-governmental organisations (NGOs) and civil society. The Rischard model was apposite, TJCB argued, because it would be quick to set up, inclusive rather than club-like, responsive, flexible and equitable, encouraging initiation and leadership from the South.<sup>145</sup>

Early 2006 saw a further change. Writing in the *International Journal of Biotechnology* and this time citing Anne-Marie Slaughter's work on government networks (again, see Chapter 3), TJCB stated that although the proposed network should still include actors from international organisations, NGOs, businesses and other sectors (academia is not listed), it would be "underpinned by governments" in order to garner legitimacy and accountability. Collaboration between actors, to be facilitated through strong leadership and inclusive membership, would provide a second key to legitimacy. This article, the last publication on the GGI, described the project as "still on the drawing board."<sup>146</sup> Despite TJCB's emphasis on urgency and speed, then, it seems that the setting up period has been rather protracted. This is further illustrated by a claim TJCB made back in 2004:

We are now in the process of bringing together some of the best creative minds from these fields [industry, academia, civil society, government] to begin the dialogue and to learn from their experiences so that any decision-making will come from the bottom up.<sup>147</sup>

The latest indications (via personal communication<sup>148</sup>) are that the GGI has not yet been officially formed and perhaps never will be.

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<sup>145</sup> Acharya *et al*, "Better Global Governance to Promote Genomics for Development," 5. In its publications on the GGI, TJCB cites Rischard's paper "High Noon: We Need New Approaches to Global Problem-solving, Fast," *Journal of International Economic Law* 4 (September 2001): 507-525. TJCB seems to borrow directly from Rischard in its arguments concerning the inefficacy and unwieldiness of existing global governance mechanisms. As illustrated at 2.3.1.2, however, it is connected with more than one agency of the UN. In *Genomics and Global Health* it suggests the UN system could play a role in promoting genomics as a GPG. (Acharya *et al*, *Genomics and Global Health*, 45.)

<sup>146</sup> Dowdeswell *et al*, *op cit*, 138 and 140.

<sup>147</sup> Acharya *et al*, "Better Global Governance to Promote Genomics for Development," 6.

<sup>148</sup> Email, 15 January 2007.



## 2.3.4 Content and Implementation

This section examines how the UNESCO declarations and associated implementation programmes, as well as the proposed activities of the GGI, might address the genetics and bioethics issues highlighted in 2.2 and 2.3.

### 2.3.4.1 *Content of the UNESCO declarations*<sup>149</sup>

All three declarations aim to promote human dignity, human rights and fundamental freedoms in the context of genetics and bioethics, while at the same time embracing principles of responsibility, solidarity, equality and justice.<sup>150</sup> They cover both medical and research ethics; article 5 of the UDHGHR (1997) refers to “research, treatment or diagnosis affecting an individual’s genome,” for example.<sup>151</sup> (Note, however, that this thesis focuses mainly on their provisions regarding research ethics.)

There are commonalities between all three UNESCO declarations. Each contains articles on informed consent, risks and benefits, confidentiality, freedom of research, ethics committees and bioethics education and training. The IDHGD (2003) and the UDBHR (2005) also cover transnational practices and the monitoring and management of research. As well as these general provisions, the two genetics declarations include principles specific to their context; both, for example, condemn discrimination on the basis of genetic characteristics and genetic reductionism. The UDHGHR (1997) also disallows reproductive cloning and states that the human genome, the ‘heritage of humanity’, in its natural state should not enable financial gain.<sup>152</sup>

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<sup>149</sup> The articles of the declarations relevant to this thesis are reproduced in Appendix I.

<sup>150</sup> This is affirmed in the preamble of each declaration.

<sup>151</sup> UDHGHR, article 5.

<sup>152</sup> Ibid, articles 1 and 4.

The declarations contain several principles that are particularly pertinent to developing countries. The UDHGHR (1997) promotes research on genetically influenced endemic diseases, whilst the UDBHR (2005) endorses community engagement, the protection of individuals and groups of special vulnerability and due regard for cultural diversity and pluralism.<sup>153</sup> All three declarations display a strong commitment to benefit sharing, knowledge exchange and capacity building. Article 18 of the UDHGHR (1997), for example, reads:

States should make every effort...to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries.<sup>154</sup>

The UDBHR (2005) also directly addresses inequalities of health. Article 14, on social responsibility, pertains to social and economic rights as bioethical issues. Citing the promotion of health and social development as “a central purpose of government,” it states that progress in science and technology should advance access to healthcare, nutrition, water and improved environmental and living conditions and reductions in marginalisation, illiteracy and poverty.<sup>155</sup>

#### **2.3.4.2 Implementation of the UNESCO declarations**

When the UNESCO General Conference adopted the UDHGHR in November 1997, it also requested that appropriate measures be taken to ensure follow-up and implementation of the declaration.<sup>156</sup> Implementation guidelines specifying how the declaration’s stipulations with regard to dissemination, awareness raising, education and

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<sup>153</sup> Ibid, article 17; UDBHR, articles 6 (3), 8 and 12.

<sup>154</sup> UDHGHR, article 18. Article 18 of the IDHGD (2003) is very similar. The only difference is that where the UDHGHR reads “human genome, human diversity and genetic research,” the IDHGD reads “human genetic data and human proteomic data.” The UDBHR (2005) is different again, as follows: “Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.” (Article 24 (2).)

<sup>155</sup> UDBHR, article 14.

<sup>156</sup> UNESCO, *Birth of the Universal Declaration on the Human Genome and Human Rights*, 17.



training should be enacted by states, UNESCO and other organisations and individuals involved in human genetics were consequently endorsed at the next General Conference in November 1999.<sup>157</sup> Similar implementation guidelines have been drafted for the IDHGD (2003), but have not yet been adopted.

UNESCO's Division of the Ethics of Science and Technology runs four main projects designed to enable member states to develop their capacity in bioethics. Firstly, it hosts a database of ethics information, the Global Ethics Observatory (GEObs). Secondly, it promotes bioethics education, through teacher training and curriculum development. Thirdly, it supports the setting up of ethics committees and their subsequent operations. Fourthly, it raises awareness and stimulates public debate on ethical issues in science and technology.<sup>158</sup> Also intended to be of use to member states are the IBC's reports on a wide range of topics in bioethics, such as pre-implantation diagnosis, embryonic stem cells, genetic counselling and cooperation between developed and developing countries.<sup>159</sup> (More details on all these activities can be found in Chapter 6.) At a broader level, UNESCO has been involved in the programmes around African science and technology introduced in 2.2.2. UNESCO was instrumental in the November 2003 African Ministerial Conference that initiated the Science and Technology Consolidated Plan of Action for the African Union and NEPAD.<sup>160</sup> It also drew attention to the importance of ethics in science and technology, particularly bioethics, at preparatory meetings for the January 2007 African Union Heads of State and Government Summit.<sup>161</sup>

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<sup>157</sup> UNESCO, "The Universal Declaration on the Human Genome and Human Rights: From Theory to Practice," 9-10.

<sup>158</sup> ten Have, "The Activities of UNESCO in the Area of Ethics," 343-348. Professor ten Have directs the UNESCO Division of the Ethics of Science and Technology.

<sup>159</sup> For a full list of IBC reports see UNESCO, "Reports of the IBC," [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=2038&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=2038&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 21 June 2007).

<sup>160</sup> African Union, "Extraordinary Conference of AMCOST, 20-24 November 2006, Cairo, Egypt: Report of the Meeting of the Ministers," 3; Belfer Center for Science and International Affairs, "What's New?" [http://bcsia.ksg.harvard.edu/whatsnew.cfm?program=STPP&nt=top&pb\\_id=615](http://bcsia.ksg.harvard.edu/whatsnew.cfm?program=STPP&nt=top&pb_id=615) (accessed 25 June 2007).

<sup>161</sup> UNESCO, "Report by the Director-General on the Execution of the Programme Adopted by the General Conference," 2, 3 and Annex 1.



### **2.3.4.3 Proposed activities of the GGI**

TJCB states that the overall mission of the GGI would be to “promote and facilitate broad-based, informed and ethical decision-making about the use of genomic technologies to contribute to global health equity.”<sup>162</sup> To this end, the network would further public knowledge on genomics and provide a forum for dialogue between the public and experts. TJCB sees the GGI as a potential coordinator of the disparate bodies involved in genomics, from public-private partnerships and bilateral alliances, to regional entities such as NEPAD, to higher level international organisations: a “network of networks.” Specific activities of the GGI could include conducting foresight exercises, promoting knowledge sharing and capacity building, designing alternative funding and intellectual property mechanisms and drafting regulatory norms and principles. These norms and principles would harmonise ethical standards for genomic technology research at a global level, incorporating benefit sharing and risk minimisation. On capacity building, TJCB echoes very closely the UDHGHR (1997) provisions (see 2.3.4.1):

Participation in the GGI would promote international and intersectoral exchange of knowledge and encourage partnerships between countries (especially developing ones) to build their genomics research and development capacity and to undertake rigorous assessment of policies in the research and development investment and human resources.<sup>163</sup>

Although the GGI has never been officially established, some of TJCB’s past activities have taken on this mantle. In March 2002 TJCB ran a joint course with the African Centre for Technology Studies in Nairobi, Kenya. The course was designed to enable a diverse range of stakeholders, from academia, the media, government and civil society, to engage in discussions around genomics policy (similar courses were also held in India, Venezuela and Oman). One of the outcomes was a web- and e-mail-based Africa Genome Policy Forum for course participants. It was hoped that the forum would foster ongoing debate, but it has not really done so (see 5.2.3).<sup>164</sup>

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<sup>162</sup> Acharya *et al*, *Genomics and Global Health*, 43.

<sup>163</sup> Dowdeswell *et al*, *op cit*, 138-139.

<sup>164</sup> Smith, A *et al*, “Harnessing Genomics to Improve Health in Africa’ – An Executive Course to Support Genomics Policy.” What is slightly confusing about the AGPF is that, although from TJCB’s publications it is

## 2.4 KENYA AND SOUTH AFRICA

In the preface to UNESCO's volume on how the UDHGHR (1997) came into being, Federico Mayor, then Director-General of UNESCO, wrote: "It is now the responsibility of States to breathe life into the Declaration, *inter alia*, by reflecting it in their domestic legislation."<sup>165</sup> Since all three declarations are non-binding, the onus is on member states to effect them within their national laws, regulations or policies. The thesis examines to what extent this has taken place in two countries, Kenya and South Africa. They were chosen because of their significant involvement in human genetics and bioethics, as outlined below. (For more details on case selection see Chapter 4.)

### 2.4.1 Types of research

There is a significant level of human genetic and biomedical research taking place in Kenya, mainly under the auspices of the Kenya Medical Research Institute (KEMRI). KEMRI has research centres in various parts of the country, including the Centre for Biotechnology Research and Development and the Centre for Clinical Research in Nairobi, the Centre for Geographic Medicine Research–Coast in Kilifi and the Centre for Vector Biology and Control Research in Kisumu. Types of research include vaccine and drug trials for diseases such as HIV/AIDS, malaria, leishmaniasis, schistosomiasis and leprosy. KEMRI collaborates with the US-based Centres for Diseases Control and Prevention and Walter Reed Army Institute of Medical Research and with the Wellcome

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clear that the GGI has never been officially established, TJCB's website has in the past said something rather different. As early as November 2005, it was describing the GGI as if it was already in operation: "The GGI *established* networks of industry leaders, academics, concerned citizens, representatives from NGOs, and government officials worldwide, with particular emphasis on developing world representation" (*italics added*). Through these networks (of which the AGPF was one), TJCB intended to develop "impact initiatives" in the South. The website text was the same in July 2007; in both November 2005 and July 2007 the GGI was listed under "Past Projects". (TJCB, "Canadian Program on Genomics and Public Health," <http://web.archive.org/web/20051122102338/http://www.utoronto.ca/jcb/genomics/html/projects.htm> and [www.utoronto.ca/jcb/genomics/html/projects.htm](http://www.utoronto.ca/jcb/genomics/html/projects.htm), both accessed 5 July 2007.)

<sup>165</sup> UNESCO, *Birth of the Universal Declaration on the Human Genome and Human Rights*, III.



Trust.<sup>166</sup> Its partnership with the Trust dates back many years. As well as aiming to produce internationally competitive, locally applicable research, the programme is committed to scientific capacity building in Kenya (see 6.3.2.3).<sup>167</sup>

South Africa, like Kenya, is engaging in different forms of human genetic and biomedical research. A 2006 Department of Science and Technology publication claimed that the country was Africa's "biotechnology research powerhouse."<sup>168</sup> Research takes place at various universities, as well as in government-sponsored research centres and initiatives. Universities producing genetic and medical research include those of the Western Cape, the Witwatersrand, Cape Town, Stellenbosch, KwaZulu-Natal and Pretoria. At the University of the Witwatersrand in Johannesburg, for example, geneticists are conducting research of both medical and evolutionary interest.<sup>169</sup> The South African Medical Research Council also runs or supports various research projects, including a cancer genetics biobank.<sup>170</sup> It has six national collaborative research programmes, on topics including HIV/AIDS, tuberculosis, malaria and indigenous knowledge systems.<sup>171</sup> The National Health Laboratory Services and the National Research Foundation also fund research.<sup>172</sup>

A key strength in South Africa's research profile is its work in bioinformatics.<sup>173</sup> The University of the Western Cape houses two initiatives in this area, the South African

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<sup>166</sup> KEMRI, "Research Centres & Programmes,"

[www.kemri.org/RESEARCH%20CENTRES%20AND%20PROGRAMS.html](http://www.kemri.org/RESEARCH%20CENTRES%20AND%20PROGRAMS.html) (accessed 9 July 2007).

<sup>167</sup> KEMRI-Wellcome Trust Collaborative Research Programme, "About us: Aims," [www.kemri-wellcome.org/aims.php](http://www.kemri-wellcome.org/aims.php) and "About Us: History," [www.kemri-wellcome.org/history.php](http://www.kemri-wellcome.org/history.php) (accessed 9 July 2007).

<sup>168</sup> To illustrate this claim the Department of Science and Technology gives the following example: "In the period 1996 to 2000, South Africa produced 222 scientific articles in genetics and 459 scientific articles in microbiology. Compared with other African countries, Kenya came closest to this level of research output with 53 and 173 scientific articles respectively." (Department of Science and Technology, "Biotechnology Innovation," 5.)

<sup>169</sup> See [www.wits.ac.za](http://www.wits.ac.za), [www.uwc.ac.za](http://www.uwc.ac.za), [www.uct.ac.za](http://www.uct.ac.za), [www.sun.ac.za](http://www.sun.ac.za), [www.ukzn.ac.za](http://www.ukzn.ac.za) and [www.up.ac.za](http://www.up.ac.za), particularly the webpages of the health and medical faculties and departments (accessed 23 November 2007).

<sup>170</sup> Medical Research Council, "Annual Report: 2004," [www.mrc.ac.za/annualreport/noncommunicable.htm](http://www.mrc.ac.za/annualreport/noncommunicable.htm) (accessed 15 February 2005).

<sup>171</sup> Medical Research Council, "Our Research," [www.mrc.ac.za/research/ourresearch.htm](http://www.mrc.ac.za/research/ourresearch.htm) (accessed 9 July 2007).

<sup>172</sup> National Health Laboratory Services, "Welcome to NHLS," [www.nhls.ac.za/](http://www.nhls.ac.za/); National Research Foundation, "NRF Profile," [www.nrf.ac.za/profile/](http://www.nrf.ac.za/profile/) (both accessed 9 July 2007).

<sup>173</sup> Bioinformatics can be defined as: "The discipline encompassing the development and utilization of computational facilities to store, analyse and interpret biological data." (WHO, *Genomics and World Health*, 201.)



National Bioinformatics Institute and the National Bioinformatics Network.<sup>174</sup> The latter is one of six Biotechnology Regional Innovation Centres (BRICs), which fall under the South African government's 2001 National Biotechnology Strategy. Two other BRICs of particular relevance are the Public Understanding of Biotechnology programme and LIFElab, which aims to improve human health by providing venture capital to human genetic and biomedical research projects focusing on infectious diseases.<sup>175</sup> South Africa can also boast some private sector activity in genetics. DNAbiotec offers expertise in molecular human genetics, while Genecare runs a gene-based diagnostic service.<sup>176</sup>

#### **2.4.2 Genetics and bioethics regulation**

Regulation of research in Kenya dates back to the 1970s. The Science and Technology Act was passed in 1977, establishing the National Council for Science and Technology (NCST). The Act was amended in 1979 to enable the creation of various research institutes, including KEMRI. NCST falls under the Ministry of Education, Science and Technology,<sup>177</sup> whilst the institutes are administered by whichever parent ministry is most relevant.<sup>178</sup> In 2004 NCST published national guidelines on bioethics, the *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya*. Under the Science and Technology Act it has ultimate control over all research in Kenya. In practice, however, most of its ethical review duties have been delegated to KEMRI and other institutions.<sup>179</sup> Confusingly, the Ministry of Health has also laid claim to jurisdiction over

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<sup>174</sup> See [www.sanbi.ac.za](http://www.sanbi.ac.za) and [www.nbn.ac.za](http://www.nbn.ac.za) for more information.

<sup>175</sup> Department of Science and Technology, "op cit, 1, 2 and 4.

<sup>176</sup> See [www.dnabiotec.com](http://www.dnabiotec.com) and [www.genecare.co.za](http://www.genecare.co.za) (accessed 23 February 2006).

<sup>177</sup> In December 2005 the Ministry of Education, Science and Technology split into two ministries, the Ministry for Education and the Ministry of Science and Technology. To reflect the situation during the data collection period (October to November 2005), this thesis keeps to the single moniker. NCST is a 'semi-autonomous government agency'.

<sup>178</sup> Ministry of Education, Science and Technology, "National Science, Technology and Innovation Policy Development in Kenya," 15.

<sup>179</sup> NCST, *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya*, 2.

research ethics in recent years, with seemingly little coordination with NCST or KEMRI.<sup>180</sup>

These ambiguities and their consequences are discussed more fully in Chapters 6 and 7.

Like Kenya, South Africa has a history of bioethics regulation that spans several decades. The Human Research Ethics Committee of the University of the Witwatersrand, established in 1966, is one of the oldest in the world.<sup>181</sup> There are now 34 RECs in South Africa, mostly in universities and research institutions.<sup>182</sup> Bioethics training is provided through the regional initiatives IRENSA and SARETI and university degree programmes.<sup>183</sup> In 2004 the Department of Health published a document entitled *Ethics in Health Research: Principles, Structures and Processes*. This represents national policy on research ethics and thus supersedes the ethical guidelines of the Medical Research Council, which were first published in 1977 and brought out in their fourth and latest edition as a series of five booklets between 2000 and 2005. The Council's guidelines apply officially only to its own researchers, but in practice had become "standard reference works."<sup>184</sup>

## 2.5 EFFECTIVE GOVERNANCE

This chapter has shown how human genetic and biomedical research have the potential to contribute towards addressing the pressing global problem of inequalities of health between North and South. If this potential is to be realised ethically, adequate protection of individual research subjects must be ensured. On a grander scale, sufficient resources

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<sup>180</sup> Ministry of Health, "Second National Congress on Quality Improvement in Health Care, Medical Research and Traditional Medicine."

<sup>181</sup> Wits Health Consortium, "Institutional Review Board," [www.witshealth.co.za/Ethics/tabid/144/Default.aspx](http://www.witshealth.co.za/Ethics/tabid/144/Default.aspx) (accessed 11 July 2007).

<sup>182</sup> Department of Health, *Ethics in Health Research*, 10.

<sup>183</sup> IRENSA is the International Research Ethics Network for Southern Africa, SARETI the South African Research Ethics Training Initiative. For more details see 6.3.2.3.

<sup>184</sup> Department of Health, *op cit*, Preamble and Contributors; Medical Research Council, "Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research" (Book 2), ii and "Ethics in Health Research," [www.mrc.ac.za/mrcnews/july2005/ethics.htm](http://www.mrc.ac.za/mrcnews/july2005/ethics.htm) (accessed 23 November 2007); SA HealthInfo, "MRC Ethics Guidelines," [www.sahealthinfo.org/ethics/index.htm](http://www.sahealthinfo.org/ethics/index.htm) (accessed 22 October 2006). Note that the Department of Health document does not go into detail on HIV vaccine research, as the Interim National Health Research Ethics Committee, which compiled it, decided to approve the Medical Research Council booklet on this subject rather than duplicate the material contained therein. (Department of Health, *op cit*, 48.)



will be needed to fund research directed towards the health needs of developing countries and the provision of any interventions consequently developed. Both UNESCO and TJCB have put forward governance mechanisms to this end. Aside from external factors, their efficacy will depend partly on their systems of decision-making and implementation. The next chapter asks what insights international relations theory might provide into how successful these endeavours are likely to be in this regard.

The field of international relations, in simple terms, explores why, how and to what degree states and other actors engage with each other at international level. This chapter outlines various approaches to international relations within the broad context of global governance, namely regime theory, networked governance and cosmopolitan democracy. These approaches have been selected for their potential to offer insights into the efficacy of the UNESCO declarations on genetics and bioethics and the proposed Global Genomics Initiative as governance mechanisms. Regime theory looks at the origins, significance and future development of international cooperation. Traditionally state-centric, it is particularly pertinent to intergovernmental organisations such as UNESCO. Networked governance, as promoted in different ways by Jean-François Rischard and Anne-Marie Slaughter, has been used as a template for the GGI. Cosmopolitan democracy explores how some of the broader issues introduced in Chapter 2, such as inequalities between North and South, might be dealt with at global level.

The four approaches are all both descriptive and normative, to varying degrees. Regime theory has grown out of attempts to explain how international cooperation and collaboration arise in a world of sovereign states,<sup>1</sup> with some branches seeking to discover how current arrangements might be improved. Rischard, Slaughter and cosmopolitan democracy theorists David Held and Daniele Archibugi have explicitly normative agendas, but in expounding why the international system needs to change they describe what they perceive to be its current faults. The driving force behind the normativity of all the approaches is a recognition that certain issues, such as genetics and bioethics, extend beyond national borders. Marc Lynch articulates some of the questions around democracy this throws up:

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<sup>1</sup> State sovereignty means that states are equal in legal terms. A state is a territorially defined unit, within which external actors are denied authoritative powers.



If important processes affecting the lives of citizens transcend state borders and escape state power, then is national democracy reduced to a formality? How can citizens act politically to affect substantive outcomes whose causes lie outside state borders in the absence of effective supranational political institutions? If international institutions do develop, how can they be made responsive to the concerns of national citizens? To the extent that international institutions make and enforce authoritative decisions, can national citizens democratically participate in their processes?<sup>2</sup>

Drawing insights from regime theory, networked governance and cosmopolitan democracy, this chapter scrutinises how these challenges are currently being met and how they might be met better, in the context of the overarching research question:

What insights can international relations theory offer into the actual and potential efficacy of global governance mechanisms in genetics and bioethics, particularly with regard to developing countries?

Implicit within this question is the possibility that there may be gaps in both the explanatory and normative power of international relations theory with regard to genetics and bioethics. These theoretical gaps will be explored further in the empirical and discussion chapters, particularly with regard to how they might be addressed.

The chapter is structured as follows. Firstly, the particular approaches selected will be situated relative to international relations theory as a whole. Secondly, the concept of 'global governance', as both a present phenomenon and a normative aim, will be explored. Thirdly, the main tenets of regime theory, networked governance (as proposed separately by Rischard and Slaughter) and cosmopolitan democracy will be introduced and some conceptual clarifications made. Fourthly, the common threads and points of divergence among and between these different approaches will be discussed thematically, enabling an integrated comparison of their various strengths, weaknesses and viability in relation to global governance. Finally, how this body of theory might be applied to the UNESCO declarations and the GGI will be considered.

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<sup>2</sup> Lynch, "Globalization and International Democracy," 92.

### 3.1 INTERNATIONAL RELATIONS THEORY

International relations theory falls into several schools, realism and liberalism being two of the longest standing. The realist paradigm, which purports that nation-states are the key actors in the international arena, was dominant until the end of the Cold War. It is chiefly concerned with the quest for power.<sup>3</sup> Realists view the international system as one of anarchy, with conflicts between states inevitable as each seeks to defend its national interest (defined in terms of "survival, security, power, and relative capabilities"<sup>4</sup>), primarily through military power.<sup>5</sup> States must exercise self-sufficiency, as dependence on another actor would leave them open to exploitation. International organisations and international law are thus seen to be of limited use.<sup>6</sup> Realism has a descendant in neorealism or structural realism, of which Kenneth Waltz is most commonly recognised as the architect. Neorealism differs from its parent theory by examining the international system as a whole. Waltz argues that although the system's structure is derived from interactions between states, it comprises more than the sum of its parts, as it drives them towards certain actions and restricts them from others.<sup>7</sup>

The main opposition to realist theory within international relations has come from liberalism. Generally, liberals argue that realists place too much emphasis on conflict and too little on cooperation.<sup>8</sup> Security is often defined more broadly than under realism, to include elements such as health and education.<sup>9</sup> In a post-Cold War and globalising world, liberalism has gained ground as an alternative explanation of world affairs, as scholars have paid increasing attention to influences beyond or below that of the state. Like realism, it has a 'neo-' successor, which synthesises these two traditionally antithetical

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<sup>3</sup> Dougherty and Pfaltzgraff, *Contending Theories of International Relations*, 58.

<sup>4</sup> Holsti, "Theories of International Relations and Foreign Policy," 37.

<sup>5</sup> Kegley, "The Neoliberal Challenge to Realist Theories of World Politics," 4-5. The concept of an anarchical international society was introduced by Hedley Bull in 1966: "Whereas men within each state are subject to a common government, sovereign states in their mutual relations are not. This anarchy it is possible to regard as the central fact of international life and the starting point of theorizing about it." (Bull, "Society and Anarchy in International Relations," 77.)

<sup>6</sup> Genest, "Realism and the Problem of Peaceful Change," 71; Kegley, op cit, 4-5.

<sup>7</sup> Waltz, "Realist Thought and Neorealist Theory," 74.

<sup>8</sup> Grieco, "Anarchy and the Limits of Cooperation," 151.

<sup>9</sup> Holsti, op cit, 43.



approaches.<sup>10</sup> Neoliberal institutionalists assume that self-interested states are the principal international actors and that power differentials are important. While acknowledging the existence of anarchy, however, they hold that international institutions can “transcend the basic structural characteristics of the anarchic international system.”<sup>11</sup>

Constructivism, another school of international relations, has grown greatly in prominence in recent years. Martha Finnemore and Kathryn Sikkink see constructivism as “a different kind of theory” to realism and liberalism, as it makes no claims about the nature of agents or the content of structures. Rather, as a social theory, it investigates social life and social change.<sup>12</sup> Finnemore and Sikkink summarise this approach as follows: “Constructivists focus on the role of ideas, norms, knowledge, culture, and argument in politics, stressing in particular the role of collectively held or ‘intersubjective’ ideas and understandings on social life.”<sup>13</sup> Thus constructivism sees rules and practices as being created and sustained by mutual agreement. The institution of state sovereignty provides an example. Reflecting common understandings about the characteristics of states, it allows these actors to recognise one another.<sup>14</sup>

Regime theory, in its different forms, draws on all three of these schools, while networked governance and cosmopolitan democracy encompass elements of both neoliberalism and constructivism, in terms of the relative importance of interests and ideas. Although they differ in the significance they attach to state and non-state actors, sovereignty and power, each of these approaches has collaboration and cooperation at an international level as a central theme. Thus they can all be seen to fall within the concept of global governance.

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<sup>10</sup> Hasenclever, Mayer and Rittberger, “Interests, Power, Knowledge,” 196.

<sup>11</sup> Dougherty and Pfaltzgraff, *op cit*, 62.

<sup>12</sup> Finnemore and Sikkink, “Taking Stock,” 391 and 393.

<sup>13</sup> *Ibid*, 392.

<sup>14</sup> Ellis, “International Regimes and the Legitimacy of Rules,” 273 and 274.

### 3.2 GLOBAL GOVERNANCE

Governance comprises decision-making on rules and activities for the management of collective issues and the subsequent implementation of those decisions. The term 'global governance' derives from the Commission on Global Governance, which met in 1995 to report on the future of the United Nations.<sup>15</sup> Within international relations theory, it refers to governance within and as an output of the international system, aimed at addressing those issues that have the potential to affect everyone, irrespective of national borders. As Robert Goodin puts it, "Cross-boundary spillovers—political and moral, as well as economic and environmental—are now absolutely endemic."<sup>16</sup> Alongside states, transnational actors such as large corporations and civil society organisations are playing a part in attempts to manage these spillovers.<sup>17</sup> The approaches to global governance examined in this chapter look at how these different actors can and do come together in various institutional forms, at local, national, regional and international levels.

'Global governance' has both descriptive and normative connotations. Robert Keohane describes it as rule making and the exercise of power on a global scale, by entities not necessarily authorised to act by general consensus (with ensuing implications for legitimacy).<sup>18</sup> James Rosenau uses the same premise, but from a different angle: because governance systems lack the traditional legitimacy conferred by democratic election, for example, they can only be effective if the great majority of those they cover agree to them. In his view, then, governance has an inherent normative purpose; it is derived from shared goals rather than formal authority.<sup>19</sup> Similarly, Ernst-Otto Czempiel sees governance as

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<sup>15</sup> See *Our Global Neighbourhood: The Report of the Commission on Global Governance* (New York: Oxford University Press Inc, 1995).

<sup>16</sup> Goodin, "Globalizing Justice," 80.

<sup>17</sup> Keohane, "Global Governance and Democratic Accountability", 130-132; Ruggie, "Taking Embedded Liberalism Global," 117. Global civil society is "the domain that exists above the individual and below the state but also across state boundaries, where people voluntarily organize themselves to pursue various aims" (Wapner, "Governance in Global Civil Society," 66).

<sup>18</sup> Keohane, "Global Governance and Democratic Accountability," 132.

<sup>19</sup> Rosenau, "Governance, Order, and Change in World Politics," 4.



the capability to meet goals or needs without the legal backing or coercive threats that render traditional forms of government effective.<sup>20</sup>

These definitions articulate in different ways what Rosenau and Czempiel term “governance without government.”<sup>21</sup> Rosenau writes,

To presume the presence of governance without government is to conceive of functions that have to be performed in any viable human system irrespective of whether the system has evolved organizations and institutions explicitly charged with performing them.<sup>22</sup>

Thus the distinction between government and governance lies in the existence or otherwise of formal authority. ‘Governance without government’ describes the present international system; states are sovereign and there is no higher authority to coordinate actions and enforce rules. How global problems are or could be addressed within or without these limitations (external factors allowing<sup>23</sup>) is of central concern to the approaches to governance outlined in this chapter.

### **3.3 PARTICULAR THEORIES AND APPROACHES**

#### **3.3.1 Regime theory**

Pierre de Senarclens has commented that the notion of governance has emerged in international relations theory “in the aftermath of the debate about ‘regimes’.”<sup>24</sup> Whether or not that debate has subsided, regime theory (or, more accurately, theories of regimes<sup>25</sup>) still has much to offer in terms of describing how international bodies or groups work and

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<sup>20</sup> Czempiel, “Governance and Democratization,” 95.

<sup>21</sup> Rosenau and Czempiel co-edited the book, *Governance Without Government: Order and Change in World Politics*.

<sup>22</sup> Rosenau, op cit, 3.

<sup>23</sup> Jim Whitman has highlighted that the extent to which global governance mechanisms can address their designated problems may be dependent on external factors, such as levels of political, economic and environmental stability. (See Whitman, “Global Dynamics and the Limits of Global Governance.”)

<sup>24</sup> de Senarclens, “Governance and the Crisis in the International Mechanisms of Regulation,” 92.

<sup>25</sup> John Vogler points out that while ‘regime theory’ is a commonly used term, there is in fact not one theory of regimes but several. (Vogler, *The Global Commons*, 25.) For simplicity, the term ‘regime theory’ is used generically in this thesis.

how they might do so more effectively, particularly intergovernmental ones such as UNESCO. International regimes encompass varying levels of institutional development. They arise from efforts to develop collaborative arrangements, formally or informally, within the international system.<sup>26</sup> Where global governance refers to a broad system or world order, regimes are perceived as coalescing around fairly well-defined issues, such as world trade, environmental concerns or indeed genetics and bioethics.<sup>27</sup> Thus regimes fulfil “particular governance functions.”<sup>28</sup> Stephen Krasner and colleagues, in his 1983 edited volume on the subject, defined regimes as “sets of implicit or explicit principles, norms, rules and decision-making procedures around which actors’ expectations converge in a given area of international relations.”<sup>29</sup> UNESCO has designed such norms<sup>30</sup> and procedures to effect genetics and bioethics governance and the Global Genomics Initiative, if established, will do so.

Within a regime, the principal or official members are traditionally considered to be states.<sup>31</sup> One incentive for states to join such arrangements is the potential to enjoy “political economies of scale,” whereby problems can be addressed more efficiently from within institutions. In an international system devoid of centralised power, many potentially beneficial agreements could not be negotiated or subsequently enforced (albeit often inadequately, through proxies for power such as sanctions or shunning) if it were not for regimes.<sup>32</sup> They represent, then, a form of governance without government. Andreas Hasenclever, Peter Mayer and Volker Rittberger, in a review essay on regime theory, describe how different theorists put forward power, interests or knowledge as defining variables in regimes. They classify these approaches as realist, neoliberal and cognitivist

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<sup>26</sup> Dougherty and Pfaltzgraff, *op cit*, 436.

<sup>27</sup> de Senarclens, “Regime Theory and the Study of International Organizations,” 456.

<sup>28</sup> Vogler, *op cit*, 19.

<sup>29</sup> Krasner, “Structural Causes and Regime Consequences,” 2. This definition has been described as vague and imprecise by Friedrich Kratochwil and Oran Young respectively, while Susan Strange deemed the whole concept of regimes “woolly.” Attempted improvements have been marginal, however, according to Beth Simmons and Lisa Martin. (Kratochwil, “The Force of Prescriptions,” 685; Young, *International Cooperation*, 195; Strange, “Cave! Hic Dragones,” 342; Simmons and Martin, “International Organizations and Institutions,” 193.)

<sup>30</sup> Norms, rules or principles are common to each of the theories or approaches described in 3.3. See 3.4.1 for a discussion of what is understood by these terms for the purposes of this thesis.

<sup>31</sup> Young, “Rights, Rules, and Resources in World Affairs,” 6.

<sup>32</sup> Caporaso, “Toward a Sociology of International Institutions,” 482.



respectively (cognitivism mirroring constructivism, see 3.1).<sup>33</sup> Realist regime theory sees regimes as formed around and influenced by the power and interests of a dominant state or group of states. International cooperation is believed to occur infrequently, states being concerned about relative gains, the potential for defection and the vulnerability that comes with interdependence.<sup>34</sup> Neoliberal regime theory, according to Hasenclever *et al*, has become the mainstream approach to regimes. While not disregarding power differentials, it portrays states as “rational egoists” who pursue absolute gains. States will therefore cooperate to realise mutual or common interests.<sup>35</sup> The “core insight” of cognitive regime theory, as explained by Stephan Haggard and Beth Simmons, is that cooperation is affected not only by power and interests but also values, beliefs and knowledge. As regimes are based on shared principles and understandings, they are intersubjective; the issue areas around which they converge are not pre-ordained. Thus cognitive approaches help to explain the evolution and content of regimes.<sup>36</sup>

This thesis incorporates elements of all three approaches to regime theory. Respecting power, the relative influence of developed and developing countries on the UNESCO declarations will be investigated. This will be primarily in function of the negotiation process, in terms of how member states worked to secure their interests. As will be shown in Chapters 5 and 6, states had a mutual interest in designing declarations, but disagreed on what norms these were to promulgate. This is where knowledge and values will become relevant, with regard to how some ideas in genetics and bioethics may have

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<sup>33</sup> Hasenclever, Mayer and Rittberger, “Interests, Power, Knowledge,” 178. This paper was published in 1996 and formed the basis of their 1997 book, *Theories of International Relations*. Their typology is one of several. Stephan Haggard and Beth Simmons (1987) grouped the regime literature into four “families”: ‘structural’ (power-based), ‘game-theoretic’ and ‘functional’ (both interest-based) and ‘cognitive’. The approaches Hasenclever *et al* term neoliberal and cognitivist have the most varied classification. Keohane (2006) describes these as ‘functional’ and ‘constructivist’ (although in a 1988 paper he used ‘rationalistic’ and ‘reflective’), while Young distinguishes between ‘contractarian’ and ‘constitutive’ perspectives. (Haggard and Simmons, “Theories of International Regimes,” 498; Keohane, “Accountability in World Politics,” 76; Keohane, “International Institutions,” 379; Young, *Governance in World Affairs*, 4.)

<sup>34</sup> Zacher (with Sutton), *Governing Global Networks*, 2-3.

<sup>35</sup> Ibid, 2; Hasenclever, Mayer and Rittberger, “Interests, Power, Knowledge,” 183-184.

<sup>36</sup> Haggard and Simmons, *op cit*, 509-510; Kratochwil and Ruggie, “International Organization,” 764 (this paper is oft-cited on cognitivism). The neoliberal and cognitivist approaches do not have to be mutually exclusive. In his seminal work *After Hegemony*, Keohane wrote, “But regimes can also affect state interests, for the notion of self-interest is itself elastic and largely subjective. Perceptions of self-interest depend on actors’ expectations of the likely consequences that will follow from particular actions and on their fundamental values. Regimes can certainly affect expectations and may affect values as well.” (63) Similarly, Young states, “It is perfectly possible to adopt the view that actors and institutions are mutually constitutive.” (Young, *Governance in World Affairs*, 4.)



shaped the formation of the declarations and vice versa, such as the human genome as the heritage of humanity and social responsibility as a bioethical principle. Central to the analysis will be a question posed by Haggard and Simmons: "Do regimes 'matter'?" That is, do regimes independently influence state behaviour? Along with several other theorists, Haggard and Simmons see empirical research at national level as crucial in answering this question.<sup>37</sup>

### 3.3.2 Global Issues networks

As shown in Chapter 2, Peter Singer, Abdallah Daar and others at TJCB have used Jean-François Rischard's ideas about networked governance in their plans for the GGI. In his book *High Noon*,<sup>38</sup> published in 2002, Rischard juxtaposes rapid global changes with what he perceives to be the slow, linear evolution of international institutions striving to cope with them and the struggle of nation-states to maintain sovereignty as a plethora of (environmental and economic) issues extend beyond borders. This dichotomy produces a "dangerous governance gap," which Rischard proposes to address through networked governance.<sup>39</sup> He identifies twenty issues, including infectious diseases and biotechnology, that he considers both global in nature and in need of urgent action and lays out a framework for addressing these, with each issue to engender a separate 'global issues network' (GIN). The networks would create new public space. Each would evolve through three phases: a constitutional (that is, setting up) phase, a norm-producing phase and an implementation phase. Made up of experts from governments, NGOs and

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<sup>37</sup> Haggard and Simmons, op cit, 492 and 513. A decade on Simmons, with Lisa Martin, reformulated the question to ask not just whether but also how regimes matter, but again lamented the lack of research at domestic level. (Martin and Simmons, "Theories and Empirical Studies of International Institutions," 747 and 756.) Others who have highlighted the paucity of research in this area include Vogler (op cit, 161) Kal Raustiala ("Governance in World Affairs," 805), Helen Milner ("International Theories of Cooperation Among Nations," 496) and, in the particular context of non-binding instruments such as the UNESCO declarations, Dinah Shelton ("Editor's Concluding Note," 556).

<sup>38</sup> Rischard's book is far from a theoretical examination of international relations. The World Bank's vice-president for Europe at the time of writing, Rischard describes himself as a "practitioner and generalist" and believes these attributes may give him an advantage over "specialized research types" in seeing the "big picture." (Rischard, *High Noon*, x.) While TJCB cites an earlier paper of Rischard's in its publications on the GGI (see Chapter 2, note 145), his book has been chosen as the primary source for this theoretical chapter as it expounds the ideas articulated in the paper more fully.

<sup>39</sup> Rischard, op cit, 38, 41, 45-46 and 57.



businesses and facilitated chiefly by intergovernmental organisations (IGOs), the networks would produce norms and standards and then rate compliance among both state and non-state actors. In the norm-producing and implementation phases they would seek the wider participation of anyone with an interest in their given issue through internet polling.<sup>40</sup>

If established, GINs would be a highly specified example of a wider and already existing phenomenon, global public policy networks, as theorised by Wolfgang Reinicke and colleagues. Rischard himself describes GINs as a "subclass of GPPNs."<sup>41</sup> Reinicke charts the emergence of these networks from the 1990s onwards, defining them as:

Loose alliances of government agencies, international organizations, corporations, and elements of civil society such as nongovernmental organizations, professional associations, or religious groups that join together to achieve what none can accomplish on its own.<sup>42</sup>

The thesis focuses on GINs rather than GPPNs more generally because the proposed GGI is explicitly modelled on the former, although many of the potential attributes and activities of GINs, as suggested by Rischard, are similar to those observed by Reinicke and colleagues in existing GPPNs, such as the Global Environment Facility and the Roll Back Malaria initiative. These include non-hierarchical and flexible structures, decision-making by consensus, developing norms and standards (but not legislation) and working with IGOs.<sup>43</sup>

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<sup>40</sup> Ibid, 66 and 171-179. The membership of a GIN might resemble that of an 'epistemic community', defined by Peter Haas as "a network of professionals with recognized expertise and competence in a particular domain or issue-area." Although these professionals may come from various backgrounds, they share the same norms, principles and practices. Thus the difference between epistemic communities and the proposed GINs would seem to be that, whilst the former emerge organically around already shared norms and beliefs, as decision-makers solicit knowledge and advice from recognised experts in particular fields, the latter would be explicitly constituted to negotiate norms among those with different areas of expertise in specific issues, with the express purpose of influencing the behaviour of both state and non-state actors. (See Haas, "Introduction: Epistemic Communities and International Policy Coordination," 3-4.)

<sup>41</sup> Rischard, op cit, 224-225.

<sup>42</sup> Reinicke, "The Other World Wide Web," 44.

<sup>43</sup> Ibid, 46, 50-51 and 54; Benner, Reinicke and Witte, "Multisectoral Networks in Global Governance," 196.

### 3.3.3 Government networks

Anne-Marie Slaughter, in her book *A New World Order* (2004),<sup>44</sup> proposes a form of networked governance that, like Rischard's, has been taken up by the proponents of the GGI. (Indeed, in one publication they describe themselves as "building on the work of Slaughter."<sup>45</sup>) The book is part descriptive, part prescriptive: Slaughter analyses how government officials network on a global level at present and how they might do this more effectively. Officials from all branches of government form networks on a global scale, exchanging information and coordinating activities. These government networks are, Slaughter writes, "a key feature of world order in the twenty-first century, but they are underappreciated, undersupported, and underused to address the central problems of global governance."<sup>46</sup>

Slaughter's premise is that in the international arena the state, contrary to the model assumed by many international relations theorists and multilateral negotiators alike, is not a unitary actor.<sup>47</sup> Rather, the state is disaggregated, primarily along legislative, regulatory and judicial lines; members of distinct domestic government institutions are increasingly involved in activities beyond national borders, interacting with their counterparts in other countries and at supranational level.<sup>48</sup> Slaughter defines a government network broadly, as "a pattern of regular and purposive relations among like government units working across the borders that divide countries from one another and that demarcate the

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<sup>44</sup> Slaughter describes 'world order' as follows: "A system of global governance that institutionalizes cooperation and sufficiently contains conflict such that all nations and their peoples may achieve greater peace and prosperity, improve their stewardship of the earth, and reach minimum standards of human dignity." (Slaughter, *A New World Order*, 15.)

<sup>45</sup> Dowdeswell *et al*, "Realising the Promise of Genomics," 138.

<sup>46</sup> Slaughter, *op cit*, 1.

<sup>47</sup> *Ibid*, 12-13. This assumption is common in studies of international relations and lies behind the prompts of various commentators towards more research on the effects of regimes at national level and vice versa (see note 37). Exceptions are the volume edited by David Victor, Kal Raustiala and Eugene Skolnikoff on environmental regimes and Andrew Moravcsik's work on the origins of international human rights law. (See Victor, Raustiala and Skolnikoff, *The Implementation and Effectiveness of International Environmental Commitments*; Moravcsik, "Explaining International Human Rights: Liberal Theory and Western Europe," *European Journal of International Relations* 1 (2) (1995): 157-189; and Moravcsik, "The Origins of Human Rights Regimes: Democratic Delegation in Postwar Europe," *International Organization* 54 (2) (2000): 217-252.)

<sup>48</sup> Slaughter, *op cit*, 5-6, 12-13 and 31.



'domestic' from the 'international' sphere."<sup>49</sup> Networks involving only domestic government officials are horizontal; those that include officials from supranational institutions to which sovereignty has been delegated (such that relevant national bodies are directly answerable to them) are vertical.<sup>50</sup> At present, government networks "contribute" to world order by stimulating policy convergence among states, perhaps leading to a more formal international regime over time; by encouraging adherence to international treaties and customary law; and by promoting international cooperation.<sup>51</sup>

Slaughter suggests that the current remit of government networks could be expanded if they were to be recognised as "prime mechanisms of global governance."<sup>52</sup> Like Rischard, Slaughter envisages a form of networked governance that would include non-state actors such as international organisations, corporations and civil society organisations. Significantly, however, Slaughter's networks would have government networks as their centrepieces. Slaughter claims that viewing the world as one of disaggregated states enables the imagining of "a genuinely new set of possibilities for a future world order," the "building blocks" of which would not be states but parts of states.<sup>53</sup> She describes what shape this conceptual framework might take thus:

A disaggregated world order would be a world latticed by countless government networks. These would include horizontal networks and vertical networks; networks for collecting and sharing information of all kinds, for policy coordination, for enforcement cooperation, for technical assistance and training, perhaps ultimately for rule making. They would be bilateral, plurilateral, regional, or global. Taken together, they would provide the skeleton or infrastructure for global governance.<sup>54</sup>

Slaughter proposes a set of what she terms 'constitutional norms' to govern this system, comprising global deliberative equality, positive comity, legitimate difference, checks and balances and subsidiarity.<sup>55</sup> Each network would also be governed by its own set of more

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<sup>49</sup> Ibid, 14.

<sup>50</sup> Ibid, 13 and 163. Note that IGOs can also act as horizontal network hosts. (Ibid, 22.)

<sup>51</sup> Ibid, 24.

<sup>52</sup> Ibid, 25.

<sup>53</sup> Ibid, 6.

<sup>54</sup> Ibid, 15-16.

<sup>55</sup> Ibid, 29-30.

specific norms. Both types will be explored more fully in the thematic discussion (and in 3.4.1 below).

### 3.3.4 Cosmopolitan democracy<sup>56</sup>

The purpose of cosmopolitan democracy is captured pithily by Daniele Archibugi: “To globalize democracy while, at the same time, democratizing globalization.”<sup>57</sup>

Cosmopolitan democracy thus embraces fully the idea of transboundary problems; indeed, David Held uses genetic engineering as an example of an issue that is inherently borderless and therefore needs global governance.<sup>58</sup> There are also synergies with the arguments for a broad security agenda based on rational self-interest introduced at 2.1.3.<sup>59</sup> These synergies between the bioethics and global governance literatures have not yet been recognised, however.

Cosmopolitan democracy hinges on the premise that the world is made up of “overlapping networks of power” and “overlapping communities of fate” that do not fit neatly within state boundaries, causing strain in the current global system.<sup>60</sup> The fates of distant communities are interwoven, thus local level economic, social or environmental issues and events can have global ramifications and vice versa.<sup>61</sup> “The intimate connection between ‘physical

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<sup>56</sup> In his 2004 book *Global Covenant*, Held refers to the project of ‘global social democracy’. For purposes of clarity, however, the term ‘cosmopolitan democracy’ will be used throughout this thesis, as Held returns to it in a 2006 paper. (Held, *Global Covenant*, 16; Held, “Reframing Global Governance,” 173.) The main chapter of *Global Covenant* expounding the global social democracy project is a developed version of Held’s 2004 paper “Democratic Accountability and Political Effectiveness from a Cosmopolitan Perspective.” (Held, *Global Covenant*, xvii.)

<sup>57</sup> Archibugi, “Cosmopolitan Democracy and its Critics,” 438.

<sup>58</sup> Held, *Global Covenant*, x.

<sup>59</sup> Held calls for the global security and human rights agendas to be connected within a “coherent international framework,” contending that any action against terrorism should be undertaken as part of a wider process of reform addressing “the insecurity of life” in developing countries. This is reminiscent of Solomon Benatar’s arguments for expanding the ethics discourse to take account of “global security” against “common global risks.” Benatar writes, “In this context, and with a deeper understanding of the impact of adverse forces shaping the wealth and health of nations, we need to appreciate how we are all deeply implicated in the lives of others, and cannot hide with moral credibility behind the barrier of physical distance while billions live impoverished lives.” (Held, “Reframing Global Governance,” 168-169; Benatar, “Bioethics: Power and Injustice,” 391.)

<sup>60</sup> Held, “From Executive to Cosmopolitan Multilateralism,” 161 and 167; Archibugi, “Cosmopolitan Democracy and its Critics,” 443-444.

<sup>61</sup> Held, “From Executive to Cosmopolitan Multilateralism,” 162.



setting', 'social situation' and politics, which distinguished most political associations from pre-modern to modern times, has been ruptured."<sup>62</sup> The ensuing risk that national level democracy will be "hollowed out," as Archibugi puts it, has engendered a questioning of the assumption that democracy must be contained within domestic borders; why, indeed, should it not extend beyond borders, thereby becoming 'cosmopolitan'?<sup>63</sup> Despite much scepticism,<sup>64</sup> the concept of cosmopolitan democracy has grown rapidly within international relations theory since its relatively recent inception. As noted by William Scheuerman, "a series of path-breaking publications ... have garnered a remarkable amount of scholarly attention in a brief span of time."<sup>65</sup>

Cosmopolitan democracy is described by Archibugi as a "political project," a term that denotes both its normative aspirations (he also uses the phrase "cosmopolitan dreams") and its potential to bear tangible fruit. The project would aim to regulate the dynamics of globalisation at the transnational level, particularly in those areas where regulation through democratic means would be difficult, if not impossible, at the state level.<sup>66</sup> This would include the provision of those public goods that "have to be provided regionally and globally if they are to be provided at all."<sup>67</sup>

Representative democracy would not be replicated directly; a global government *per se* is not envisaged.<sup>68</sup> Rather, the project "attempts to specify the principles and the institutional arrangements for making accountable those sites and forms of power which presently operate beyond the scope of democratic control."<sup>69</sup> Held articulates the three fundamental principles of cosmopolitanism as follows: individuals, as opposed to states or other entities, are "the ultimate units of moral concern"; everyone's equal worth must be acknowledged; and rules and principles

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<sup>62</sup> Held, "Democratic Accountability and Political Effectiveness," 365.

<sup>63</sup> Archibugi, "Demos and Cosmopolis," 28. Mathias Koenig-Archibugi uses the same "hollowed out" terminology in "Globalization and the Challenge to Governance," 4. 'Cosmopolitan' carries similar connotations to 'global', in the sense of being applicable to everyone, irrespective of national borders.

<sup>64</sup> Archibugi, "Demos and Cosmopolis," 29-30, 33-34 and 36.

<sup>65</sup> Scheuerman, "Cosmopolitan Democracy and the Rule of Law," 439.

<sup>66</sup> Archibugi, "Demos and Cosmopolis," 28 and 34.

<sup>67</sup> Held, *Global Covenant*, 16.

<sup>68</sup> Archibugi, "Demos and Cosmopolis," 29.

<sup>69</sup> Held *et al*, *Global Transformations*, 449.

must be impartial and thus universally shared.<sup>70</sup> Governance at the international level would not always be the most appropriate means to fulfil these, nor would the requisite level for any given issue be obvious or natural.<sup>71</sup> Democracy would in fact be promoted at several mutually supportive levels—inside nations, among states and transnationally—and involve both state and non-state actors.<sup>72</sup>

### 3.4 CONCEPTUAL CLARIFICATIONS

Some concepts cut across some or all of the approaches outlined above and thus need to be clarified theoretically before the discussion proceeds. These are norms, efficacy or effectiveness and global public goods.

#### 3.4.1 Norms

Norms, rules and principles are central features of each of the approaches described above, as they are of the UNESCO declarations and the proposed GGI. Thus what exactly is meant by these terms needs elucidating. Norms can be thought of as either regular or prescribed patterns of behaviour, which generate expectations as to what will or ought to be done in a given situation.<sup>73</sup> Finnemore and Sikkink identify three categories of norms: regulative, constitutive and evaluative or prescriptive. Regulative norms constrain or order behaviour, constitutive norms create new actors, interests and types of action and evaluative or

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<sup>70</sup> Held "From Executive to Cosmopolitan Multilateralism," 169. Christian van den Anker similarly articulates individualism, universalism and generality as the three principles commonly recognised as cosmopolitan. (van den Anker, "Institutional Implications of Global Justice as Impartiality," 270.) In other publications on cosmopolitan democracy, Held expands these to a set of eight more specific principles that would fulfil the third cosmopolitan principle of impartiality and universalism, namely equal worth and dignity, active agency, personal responsibility and accountability, consent, decision-making through voting, inclusiveness and subsidiarity, avoidance of serious harm and sustainability. (Held, *Global Covenant*, 171; Held, "Democratic Accountability and Political Effectiveness," 389; Held, "Law of State, Law of Peoples," 25.)

<sup>71</sup> Held, *Global Covenant*, 108.

<sup>72</sup> Archibugi, "Principles of Cosmopolitan Democracy," 209.

<sup>73</sup> Hurrell, "Norms and Ethics in International Relations," 143.



prescriptive norms encapsulate the 'oughtness' that distinguishes norms from "other kinds of rules."<sup>74</sup> This thesis is mainly concerned with regulative and prescriptive norms, both within governance mechanisms and as outputs of them.

In the context of the "regime architecture" of cooperative security, Abram and Antonia Chayes define norms generically, as "a broad class of generalized prescriptive statements—rules, standards, principles, and so forth—both procedural and substantive."<sup>75</sup> Under Krasner's classic definition of regimes (stated above), however, a careful distinction is drawn between the norms and principles that dictate a regime's overall ethos and the rules and decision-making procedures that prescribe or proscribe specific actions and practices.<sup>76</sup> Friedrich Kratochwil criticises this hierarchy as overly simplistic, having observed some overlap between the four categories in actual examples of regimes.<sup>77</sup> In the context of the non-binding governance mechanisms under discussion, all four categories encapsulate a degree of 'oughtness'. Furthermore, UNESCO appears to equate norms and principles with rules, as does TJCB in its plans for the GGI. Hence the thesis does not make sharp delineations between these terms.

Krasner holds that "diffuse" principles and norms such as sovereignty underpin many international regimes, irrespective of the issue at hand.<sup>78</sup> These principles govern activities within an organisation, as opposed to those emanating from it. Analogous schemata are found within the normative networked governance and cosmopolitan democracy approaches. Each global issues network (GIN) would draw up a code of conduct in its 'constitutional phase', based on shared best practices in organisation, communication and operationalisation and principles such as 'global citizenship'. This code of conduct would then govern the 'norm-producing

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<sup>74</sup> Finnemore and Sikkink, "International Norm Dynamics and Political Change," 891.

<sup>75</sup> Chayes and Chayes, "Regime Architecture," 68.

<sup>76</sup> Krasner, "Structural Causes and Regime Consequences," 2-3.

<sup>77</sup> Kratochwil, *Rules Norms, and Decisions*, 59.

<sup>78</sup> Krasner, "Structural Causes and Regime Consequences," 17-18. Finnemore and Sikkink deem sovereignty a collection of norms rather than a single norm, encapsulated in a variety of rules and practices over time. (Finnemore and Sikkink, "International Norm Dynamics and Political Change," 891.)

phase'.<sup>79</sup> Similarly, global 'constitutional norms' would ordain how members of government networks should treat one another, as "fellow participants in, and constituents of, a world order."<sup>80</sup> Cosmopolitan democracy would articulate universal or organising principles to "disclose the proper framework for the pursuit of argument, discussion and negotiation about particular spheres of value." No one, whether a state or non-state actor and whether operating at national or international level, would be immune from these "cosmopolitan values and standards."<sup>81</sup>

The norms considered above deal with internal governance. A second order of norm, namely those prescribing actions or rules in function of the particular issues around which actors have converged, is equally pertinent to the four global governance approaches. In this context, Kratochwil writes on regimes, "If the members of the international community decide that a particular issue is supposed to be governed by particular norms, a regime emerges."<sup>82</sup> A GIN would devise a regime-like "package" of norms, standards or policy recommendations in its 'norm-producing phase', while government networks would formulate 'network norms' targeted expressly at government officials.<sup>83</sup> The cosmopolitan democracy blueprints do not lay out plans for norm development *per se*, although a global assembly would lay down standards around urgent global problems, to embed "the minimum conditions for human agency to flourish."<sup>84</sup>

How norms have been constructed and promoted, where they are situated and at whom they are aimed affects the extent to which they are accepted and applied. Finnemore and Sikkink describe the "life cycle" of norms as comprising three stages: emergence, acceptance and internalisation. Which stage has been reached

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<sup>79</sup> Rischard, *op cit*, 173-174.

<sup>80</sup> Slaughter, *op cit*, 29 and 259.

<sup>81</sup> Held, *Global Covenant*, 170-171 and 178.

<sup>82</sup> Kratochwil, "Contract and Regimes," 82.

<sup>83</sup> Rischard, *op cit*, 173 and 176; Slaughter, *op cit*, 25 and 195-196.

<sup>84</sup> Held, *Global Covenant*, 109.



dictates the relative influence of the norm.<sup>85</sup> This can be observed in the UNESCO declarations, in that the well-established bioethical principles they uphold (informed consent, for example) are already found in national systems, whereas newer ideas, such as progress in science and technology as a bioethical construct, have thus far emerged and been accepted internationally, but have yet to be internalised (see Chapter 6 for more details). The structure of an organisation will influence the content, force and application of the norms it embodies; institutionalisation of norms usually precedes acceptance, as prospective and current members become socialised as to expected behaviour.<sup>86</sup> The reasons why states or other actors might choose to comply with norms, rules or principles fall into two categories: self-interest and rightful obligation. These do not have to be mutually exclusive; enforcement may engender consistent compliance such that a norm becomes internalised, or equally the desire to do what is right may gradually dissipate if norm infringements by others go unpunished.<sup>87</sup>

Sceptics would argue that “powerful actors can always find a norm to support their consequentially based choice.”<sup>88</sup> Hence which norms are dominant often reflects the distribution of power among states.<sup>89</sup> As Slaughter points out, however, norms also constrain power: “Power without norms is both dangerous and useless. It is dangerous because of the risk of abuse. It is useless because it lacks purpose. The answer in both cases is to harness power and to constrain it through norms.”<sup>90</sup> Although at a basic level norms limit choices, they can also empower collective action and enable new forms of activity.<sup>91</sup> This would be the case should the articles on capacity building and knowledge sharing in the UNESCO declarations be fulfilled, for example. Furthermore, norm development continues after formal negotiations have ended, as the institutions in which the norms are housed (such as

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<sup>85</sup> Finnemore and Sikkink, “International Norm Dynamics and Political Change,” 895.

<sup>86</sup> Ibid, 899-900; Hurrell, op cit, 128.

<sup>87</sup> Fearon and Wendt, “Rationalism v. Constructivism,” 61-62.

<sup>88</sup> Hurrell, op cit, 143.

<sup>89</sup> Ibid, 146; Schmitz and Sikkink, “International Human Rights,” 522.

<sup>90</sup> Slaughter, op cit, 215.

<sup>91</sup> Hurrell, op cit, 142-143.

the UNESCO Bioethics Programme) encourage application and grapple with new problems.<sup>92</sup>

Some view ethical and human rights-based norms as fundamental and thus timeless and immutable, rather than as negotiated and evolving values or rules.<sup>93</sup> In this vein, Rischard states that GINs would make a “constant appeal to universal values” in the governance of their decision-making procedures, without specifying from where these values would derive. In direct contrast, Finnemore and Sikkink argue that “norms do not appear out of thin air,” but are actively constructed.<sup>94</sup> To what extent norms can or should be universal is also contested. At international level, there is a tension between norms that mediate between different values and those that enforce universal ones.<sup>95</sup> UNESCO illustrates this tension in its declarations, in that it claims to promulgate universal norms, but acknowledges that these will be applied differently, according to socioeconomic and cultural circumstances. To what extent international norms are internalised, by being incorporated into national systems, is a key question in this thesis. As Finnemore and Sikkink argue, “International norms must always work their influence through the filter of domestic structures and domestic norms.” This process can result in variations in compliance and interpretation, particularly if norms are ambiguously worded.<sup>96</sup>

To summarise, based on the various understandings articulated in different approaches to international relations, as well as by UNESCO and TJCB, this thesis considers two types of norms. Firstly, it examines those that govern procedures at international level, both explicitly and implicitly (including how these norms are

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<sup>92</sup> Ibid, 147.

<sup>93</sup> O'Neill, “The Dark Side of Human Rights,” 434; Konrad, “Norms, Values and Trans-Cultural Medical Ethics,” 14. One commentator on the 1997 UNESCO declaration on the human genome seems to take this view: “The Declaration is timeless... We can expect that the Declaration will, in due time, be modified. But as the text is drafted the principles are as true today as they always were and as they always will be in the future.” (Byk, “A Map to a New Treasure Island,” 236.)

<sup>94</sup> Finnemore and Sikkink, “International Norm Dynamics and Political Change,” 896.

<sup>95</sup> Hurrell, op cit, 149.

<sup>96</sup> Finnemore and Sikkink, “International Norm Dynamics and Political Change,” 893; Hurrell, op cit, 143.



themselves decided upon). Secondly, it analyses the outputs of these decision-making procedures, in terms of negotiated standards of behaviour related to specific issues (which may invite censure or sanction if violated). How influential both types of norms are will depend on whether they are considered legitimate in content and origin and on the relative power of the actors at which they are aimed.

### 3.4.2 Efficacy

Jon Vogler writes in *The Global Commons*, "The question of effectiveness should be at the heart of any discussion of regimes."<sup>97</sup> Although much of the literature on effectiveness sits within analyses of environmental regimes, it can be extrapolated to apply to global governance more generally. It may seem intuitive to measure efficacy according to whether a governance mechanism appears to solve the problem it is intended to address, but there are problems with this approach.<sup>98</sup> Whether or not issues are resolved may have more to do with their nature, complexity and extent or with external factors such as natural disasters than with a regime's strength. Spurious correlations may thus falsely accredit regimes with success or failure. Alternative measures include how far mechanisms are implemented and complied with or shape the behaviour of those targeted. These must also be used cautiously, however; an efficiently working mechanism may not be effective in addressing the problem at hand and, while behavioural analysis has the advantage of a clear link with problem solving, false causality is again a danger.<sup>99</sup>

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<sup>97</sup> Vogler, op cit, 152.

<sup>98</sup> Hasenclever, Mayer and Rittberger provide an example of this intuitive approach: "Regime *effectiveness* comprises two overlapping ideas. First, a regime is effective to the extent that its members abide by its norms and rules. Second, a regime is effective to the extent that it achieves the objectives or purposes for which it was intended." (Hasenclever, Mayer and Rittberger, "Interests, Power, Knowledge," 178.)

<sup>99</sup> Young, *Governance of World Affairs*, 109-111; Vogler, op cit, 154, 167 and 176-177; Victor, Raustiala and Skolnikoff, "Introduction and Overview," 12; Raustiala and Victor, "Conclusions," 698-699.

Taking these considerations into account, the thesis examines efficacy in terms of decision-making and implementation. Within the limitations of governance, whether the regulations and policies decided upon are the right ones will condition how far they can influence behaviour if implemented as intended. The thesis asks whether the UNESCO declarations and the GGI are or could be effective mechanisms for the governance of genetic and biomedical research, in terms of protecting research participants and addressing the health needs of developing countries. In answering these questions, care will be taken to avoid false causality. Where national level regulations and policies on genetics and bioethics are analysed, for instance, the extent to which these have been inspired by the UNESCO declarations, if at all, is critically assessed.

### **3.4.3 Global public goods**

As explained at 2.3.2.3, global public goods (GPGs) provide non-rivalrous and non-exclusive benefits across national borders. In the face of market failure, they must be supplied through collective action, with ensuing implications for international relations. Within the realist school of regime theory, hegemonic stability theory considers a regime to be a public good established by a dominant power, for which the net gains will outweigh the cost of provision.<sup>100</sup> The UNDP studies of GPGs by Kaul *et al* also see regimes as public goods: 'intermediate public goods' that will help to supply 'final public goods', such as clean air or environmental sustainability. This seems problematic on two levels. Firstly, international agreements are generally intergovernmental rather than global. Secondly, if collective action (through regimes) is deemed a public good, then the argument that GPGs require collective action for their supply becomes circular.

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<sup>100</sup> Hasenclever, Mayer and Rittberger, "Interests, Power, Knowledge," 197-198 and 204; Haggard and Simmons, *op cit*, 502-503. Both sets of authors offer summaries of various critiques of hegemonic stability theory. (See Hasenclever, Mayer and Rittberger, *Theories of International Regimes*, 95-100 and Haggard and Simmons, 503.)



2.3.2.3 showed that some commentators have lamented the broadening of the GPG concept to represent essentially any good enjoyed by the global public. UNDP's 2003 volume acknowledges that a common response to its 1999 study was that what it terms GPGs were often previously simply considered 'global concerns' or 'global challenges'.<sup>101</sup> Rischard finds the concept generally unhelpful and Slaughter does not use it.<sup>102</sup> Held, in his work on the reform of global governance, uses the term GPG in function of the 2003 UNDP study, but more usually refers to 'global problems' or 'global issues'.<sup>103</sup> This thesis takes a similar approach, drawing on several of UNDP's recommendations, but in the context of addressing global issues through global governance, rather than GPG supply.

### 3.5 THEMATIC DISCUSSION

The approaches to global governance outlined above—regime theory, networked governance through issue-based and government networks and cosmopolitan democracy—have points of convergence and divergence on key themes that will prove pertinent to the analysis of the actual and potential efficacy of the UNESCO declarations and the proposed GGI. These themes are: (1) relations between actors and issues; (2) representation, legitimacy and accountability; (3) norms, implementation and enforcement; (4) the location of governance; and (5) time and speed. Themes 2 and 3 form the basis for the empirical chapters, whilst themes 1, 4 and 5 are cross-cutting. In what follows, the actual or potential strengths and weaknesses of the various approaches to global governance are explored according to these themes, in function of the overall research question of this thesis.

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<sup>101</sup> Kaul *et al*, "Why Do Public Goods Matter Today?" 7.

<sup>102</sup> Rischard, *op cit*, 222.

<sup>103</sup> See, for example, "The Reform of Global Governance" in *Global Covenant*, 94-116.

### 3.5.1 Relations between actors and issues

As issues spread beyond borders, states and non-state actors are becoming increasingly interdependent.<sup>104</sup> Genetics and bioethics, for example, could potentially involve national and international policy-making bodies, academic institutions, the private sector and non-governmental and civil society organisations (as reflected in the data collection, see 4.2). Perspectives vary on how relations between different sectors of society work at present and how they should work. Regime theory is traditionally state-centric, often being used to analyse arrangements within intergovernmental organisations such as UNESCO.<sup>105</sup> As noted by Oran Young, however, there is “nothing out of the ordinary” about the emergence of regimes in which NGOs rather than states are the key members.<sup>106</sup>

Rischarde claims that tri-sector partnerships between governments, corporations and civil society are needed to address seemingly irresolvable global problems. Although the word ‘partnership’ implies equality of consequence, however, GINs would have no coercive power and would thus be ultimately dependent on states.<sup>107</sup> Slaughter, by contrast, while not explicitly taking the line that civil society organisations and businesses are given too much space relative to states, gives voice to those who do.<sup>108</sup> She argues that government networks have an advantage over the “global policy networks” advocated by Kofi Annan, Reinicke, Rischarde and others, in that, being composed of democratically appointed or elected officials, it is clear who is exercising power and on whose behalf. The broader policy networks of Slaughter’s version of networked governance would thus enjoy legitimacy through having these accountable government networks, responsible for final decisions, at their core.<sup>109</sup>

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<sup>104</sup> Keohane, “Global Governance and Democratic Accountability,” 131.

<sup>105</sup> Dougherty and Pfaltzgraff, op cit, 439.

<sup>106</sup> Young, “Rights, Rules, and Resources in World Affairs,” 6.

<sup>107</sup> Rischarde, op cit, 47-51 and 185.

<sup>108</sup> Slaughter, op cit, 9-10, 224-225, 240 and 262. Slaughter writes of a group of scholars criticising the involvement of non-state actors in global governance, but names only Martin Shapiro, citing his work on “experts and enthusiasts.” (See Shapiro, “Administrative Law Unbounded: Reflections on Government and Governance,” *Indiana Journal of Global Legal Studies* 8 (2) (2001): 369-378.)

<sup>109</sup> Slaughter, op cit, 4, 9, 28-29, 224 and 231.



Held emphasises that cosmopolitan democracy is based on a recognition of the enduring significance of democratic nation-states.<sup>110</sup> While granting their key role in contemporary global governance, however, he questions their efficacy in dealing with issues that extend beyond national borders. Cosmopolitan democracy thus calls for a multilayered approach to governance, to incorporate both subnational and supranational actors. Archibugi describes these relationships in cosmopolitan democracy thus: "It is a project that invokes voluntary and revocable alliances between governmental and meta-governmental institutions, where the availability of coercive power, in ultima ratio, is shared between players."<sup>111</sup> As a first step towards cosmopolitan democracy, Held and Archibugi suggest that the UN should be rejuvenated through, *inter alia*, stricter adherence to the Charter and a more fairly structured Security Council.<sup>112</sup> Beyond these measures, Held also proposes setting up regional parliaments and governance structures and an assembly of democratic states and agencies to handle global problems, legitimised to intervene directly where necessary.<sup>113</sup>

The structures of UNESCO and the proposed GGI may differ in terms of flexibility and hierarchy, as do the various approaches to global governance. Regimes can be formal or informal. In the former, non-binding instruments such as the UNESCO declarations are generally quicker to negotiate and more adaptable in terms of application and future adjustments than binding ones.<sup>114</sup> Rischard criticises what he sees as rigidity in traditional IGOs and concludes that they need to become flatter, leaner and faster at decision-making. Under his framework, each global problem would give rise to a specific network, membership of which would be based on knowledge, thereby curtailing "excessive layers of incompetence and ritual."<sup>115</sup>

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<sup>110</sup> Held, *Global Covenant*, 113.

<sup>111</sup> Archibugi, "Cosmopolitan Democracy and its Critics," 454.

<sup>112</sup> Held, *Global Covenant*, 108 and "From Executive to Cosmopolitan Multilateralism," 174-175; Archibugi, "Principles of Cosmopolitan Democracy," 221.

<sup>113</sup> Held, "From Executive to Cosmopolitan Multilateralism," 176-179 and *Global Covenant*, 110-113. These are two of a total of seven innovations Held proposes. Archibugi, citing previous collaborative work with Held and also some of Held's earlier solo writings, also suggests roles for regional organisations and an elected assembly to include civil society representatives, within the context of UN reform. (Archibugi, "Principles of Cosmopolitan Democracy," 221 and 228.)

<sup>114</sup> Victor, Raustiala and Skolnikoff, "Introduction and Overview," 8 and 18.

<sup>115</sup> Rischard, *op cit*, 42-44 and 170.

Slaughter, like Rischard, sees her networks as having the potential to represent a flexible means of global governance. She presents a check to this vision, however, in that some of the advantages of flexibility might need to be compromised to ensure respect for 'constitutional norms'.<sup>116</sup> Slaughter also highlights that networks are sometimes criticised on the grounds that their informality can allow more powerful states to dominate, because the constraints found in traditional IGOs are absent. The potential solutions proposed by Slaughter to this and other dilemmas include ensuring wider participation through broader policy networks, recognising government officials' international functions, making networks more visible, increasing the number of legislative networks and enhancing accountability at domestic level, although how these would address unequal power relations engendered by informality is far from obvious.<sup>117</sup> Held provides a final potential restraint on the call for flexibility. He makes the observation that current trends towards more fluid governing mechanisms are neither inevitable nor irreversible.<sup>118</sup> This implies that movement towards faster, less hierarchical governance does not necessarily follow the linear progression portrayed by Rischard.

Whether issues are best dealt with separately or holistically is a point of divergence among the different approaches and is relevant to whether genetics and bioethics would be best addressed as single issues or in the broader contexts of inequalities of health and development. Rischard envisages GINs acting quickly and efficiently, in contrast to traditional IGOs, because each would tackle a separate problem, thus minimising complexity through specificity.<sup>119</sup> While regimes usually coalesce around fairly well-defined issues, ambiguity concerning ownership of and responsibility for problems can result in overlapping or contradictory norms, functions and mandates among different international bodies. Lack of coherence can also lead to issues falling between agencies, or uncertainty as to whether action should be taken at global or national levels.<sup>120</sup>

Bioethics provides an example. As outlined in Chapter 2, several international

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<sup>116</sup> Slaughter, *op cit*, 29, 31 and 264.

<sup>117</sup> *Ibid*, 28-29.

<sup>118</sup> Held, "Democratic Accountability and Political Effectiveness," 366.

<sup>119</sup> Rischard, *op cit*, 170.

<sup>120</sup> Held, *Global Covenant*, 94 and 97; Hurrell, *op cit*, 143; Reinicke, "Global Public Policy," 136-137.



organisations, UN-based and otherwise, have produced guidelines or standards for ethical biomedical research. Sjef Gevers is critical of this proliferation:

Before elaborating and publishing their 'own' standards, international organisations should really ask themselves what the 'added value' is of their contribution in terms of further convergence and better protection. A mere proliferation of standards is of no use to anybody, but may only lead to confusion or even "shopping" between different international documents.<sup>121</sup>

From a different perspective, Young notes that as much as organisations having similar mandates raises the possibility of overlap and congestion, it also enables positive connections and mutual reinforcement.<sup>122</sup> A too strictly delineated remit may also deny linkages with those working on related issues.<sup>123</sup> Rischard acknowledges a potential drawback to his fast-moving, issue-specific framework in that it would not take account of such linkages, but argues that it is precisely because international negotiations recognise these that they "trade laxity on one issue against laxity on another" and thus come up with less than optimal solutions. He suggests that the constraints of pigeon-holing issues could be negated with a further network devoted to fostering exchanges between GINs, although he does not stipulate who should be involved in this.<sup>124</sup>

Slaughter, like Rischard, believes that networks would work most effectively if they were targeted: "Government networks should be explicitly designed to engage, enmesh, and assist specific government institutions."<sup>125</sup> Unlike Rischard, however, she does not acknowledge that this may prove an oversimplified model. A cross-cutting problem or issue may be best addressed by several government departments working together. Bioethics, for example, could involve ministries of health, science and technology, industry and education, to name a few (as will be shown in the cases of Kenya and South Africa in Chapters 5 and 6). Cosmopolitan democracy, in contrast to both forms of networked governance, aims to respond to global concerns in an integrated manner. Archibugi

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<sup>121</sup> Gevers, "Medical Research Involving Human Subjects," 297.

<sup>122</sup> Young, *Governance in World Affairs*, 122.

<sup>123</sup> Haggard and Simmons, *op cit*, 497.

<sup>124</sup> Rischard, *op cit*, 190-191.

<sup>125</sup> Slaughter, *op cit*, 247.

detects a strong call for global regulation of issues such as immigration, human rights, the environment, financial flows and development aid, but observes that at present each of these areas is serviced to a greater or lesser extent by its own regime. Cosmopolitan democracy offers “a working frame within which the diversity of areas which citizens and global movements are working on can be connected.”<sup>126</sup> Whether it thus has the potential to address the various governance issues in genetics and bioethics outlined in Chapter 2 as a coherent whole can therefore be explored.

### 3.5.2 Representation, legitimacy and accountability

Issues of representation, legitimacy and accountability are key to any discussion of global governance. On legitimacy Allan Buchanan and Keohane write:

It is important not only that global governance institutions be legitimate, but that they are perceived to be legitimate. The perception of legitimacy matters, because, in a democratic era, multilateral institutions will only thrive if they are viewed as legitimate by democratic publics.<sup>127</sup>

Whether institutions such as UNESCO and the proposed GGI are perceived as legitimate will depend partly on whether they are seen as representative of and accountable to stakeholders and experts in the issue at hand. Regime theorists Nayef Samhat and Jaye Ellis, Rischard, Slaughter and Held and Archibugi have all discerned deficiencies in current international relations in this regard and have thus suggested improvements, including new forms of democracy. The different approaches to relations between sectors and layers described above are played out in these assorted visions for representation, legitimacy and accountability.

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<sup>126</sup> Archibugi, “Cosmopolitan Democracy and its Critics,” 451.

<sup>127</sup> Buchanan and Keohane, “The Legitimacy of Global Governance Institutions,” 407. Buchanan and Keohane differentiate between legitimacy in the normative and sociological senses. The former denotes the right to rule, whilst the latter applies to those “widely believed to have the right to rule.” (Ibid, 405.) This thesis asks whether UNESCO and the proposed GGI, as formal and informal organisations respectively, might be able to garner both normative and sociological legitimacy (albeit through non-binding norms).



As the governance of genetics and bioethics could potentially involve a diverse array of actors, from the North and South and across sectors, whether all stakeholders are or will be adequately represented must be addressed. This reflects wider concerns within international relations about representation in global governance mechanisms. Held describes IGOs as facing a “crisis of legitimacy” on two counts: relations between strong and weak states are unequal and “chains of delegation” from the international to the national are too long. On the first issue, Held writes, “Increasingly, these institutions appear to speak for the powerful, or to be cast aside by these very same forces if they fail to fall into line with their will.”<sup>128</sup> Drawing on UNDP’s work on GPGs, he points to the power imbalances between states during international negotiations by way of example.<sup>129</sup> These can be both qualitative and quantitative; some countries can afford to make available large delegations of experts to back up their official representative, whilst others may only be able to send one person, who may not be a specialist in the field.<sup>130</sup> Slaughter makes a similar observation with regard to less formalised relations between states, highlighting concerns with inequalities in power between rich and poor countries as government officials become increasingly involved in global governance: “Shifting authority to technocrats means privileging the views of those nations that *have* technocrats—inevitably the most developed nations.”<sup>131</sup>

In their chapter in the 2003 UNDP volume, Pamela Chasek and Lavanya Rajamani outline specific difficulties faced by developing countries during international negotiations and ways in which these might be resolved. To what extent their observations apply to how the UNESCO declarations were drawn up will be explored in Chapter 5. Further to the problems concerning the size and expertise of delegations highlighted by Held, Chasek and Rajamani describe how some delegates will arrive at meetings with “hollow mandates,” having not received clear instructions as to what their countries’ negotiating

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<sup>128</sup> Held, *Global Covenant*, xiii.

<sup>129</sup> That Held draws on the UNDP volume is unsurprising, given that he and Anthony McGrew wrote one of its chapters, on political globalization.

<sup>130</sup> Held, *Global Covenant*, 95-96. Held cites Kaul *et al*, “How to Improve the Provision of Global Public Goods,” 30-31, a summary chapter of the study’s findings.

<sup>131</sup> Slaughter, *op cit*, 221.

positions should be. Moreover, if they attend only later sessions, they will not only have missed out on agenda setting, but will also lack “institutional memory” and the corresponding leverage to influence proceedings. This can be compounded for those countries without easy access to background documentation through high-speed internet connections.<sup>132</sup> The two analysts make several practical suggestions on how developing countries could be better represented at international meetings and thus have stronger mandates and bargaining positions. Firstly, countries could hold national policy debates and strategic consultations. Greater coordination between relevant ministries might also “make for more effective delegations.”<sup>133</sup> Secondly, regional preparatory meetings would aid networking among developing countries. Broad coalitions can be powerful, but given the diversity of national concerns and priorities, Chasek and Rajamani recommend that these should be complemented by smaller groups focusing on special issues. Finally, fast and reliable internet access would help improve both coordination among countries and availability of information. All these measures might be realised through a “participation fund,” as suggested in the first UNDP study by Kaul and associates.<sup>134</sup>

To what extent the UNESCO declarations (and the GGI norms, if formulated) are perceived as having been negotiated and subsequently implemented democratically will have implications for their legitimacy.<sup>135</sup> The second crisis of legitimacy that Held identifies, the “chains of delegation” between IGOs and states, he attributes to weak and obscure mechanisms of accountability, particularly with regard to international negotiations.<sup>136</sup> Samhat, Ellis, Rischard, Slaughter and Held each lay out a framework for

<sup>132</sup> Chasek and Rajamani, “Steps Toward Enhanced Parity,” 246, 248-249 and 258-259.

<sup>133</sup> Robert Putnam has characterised negotiations about international agreements as ‘two-level games’, recognising that bargaining over an agreement’s content will take place at domestic as well as international levels. Different factions within states will have divergent opinions on what would be in the ‘national’ interest. (Putnam, “Diplomacy and Domestic Politics,” 433 and 460.)

<sup>134</sup> Chasek and Rajamani, *op cit*, 246, 255 and 258-259.

<sup>135</sup> Harlan Cleveland, in a review of Rischard’s book, comments that norms that have been “arrived at by a process that’s well understood and respected” can be a powerful force for change. (Cleveland, “Solving World Problems in 20 Years,” 62.)

<sup>136</sup> Held, *Global Covenant*, 141-142. Raffaele Marchetti makes a similar observation, describing the system of “double representation” in international organisations, whereby individuals are represented by national parliaments, which in turn elect an international representative, as producing “an almost insurmountable barrier to engaging in public international life.” (Marchetti, “Global Governance or World Federalism?” 291.) Slaughter’s government networks would avoid these long chains of delegation because those negotiating agreements would also be responsible for their implementation. (Slaughter, *op cit*, 263.) This seeming efficiency may in fact constitute a dearth of checks and balances in terms of the separation of power, however.



how representation could be improved on a global scale. Both Samhat and Ellis argue from a constructivist or cognitivist perspective for increased civil society involvement in international regimes. Rischard advocates representation through experts from specific sectors combined with forms of wide participation. Slaughter, as would be expected, concentrates on government officials, but suggests they could operate from a global as well as a national mandate. Held identifies multiple potential constituencies, to be defined by who is significantly affected by a given issue rather than geographical borders.

Samhat and Ellis argue separately for international regimes to be considered as public spheres, characterised as frameworks within which interests and identities are constituted and actors engage in discussion and deliberation. Samhat believes the “democratic potential” of international regimes is growing as they involve a broadening range of actors, thus forming “transboundary political communities” around specific issues.<sup>137</sup> For Ellis, discourse within regimes enables “the articulation of international rules and norms grounded in consensus and therefore enjoying legitimacy.”<sup>138</sup> Both writers see the inclusion of civil society as the key element of regimes as public spheres. Ellis echoes Held in recommending that negotiations be made more open and thus “more permeable to influence from civil society.”<sup>139</sup> Samhat, however, contends that this is already happening, with documentation of international meetings becoming increasingly public and civil society actors now participating “across the gamut of regime and norm-building processes,” from agenda setting to compliance monitoring. He sees these actors as representative agents and thus the means by which a rudimentary form of global democracy or global citizenship is practised.<sup>140</sup> Chapters 5 and 6 will explore how far this favourable assessment might be applied to UNESCO or the proposed GGI.

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<sup>137</sup> Samhat, “International Regimes and the prospects for Democracy,” 180 and 186.

<sup>138</sup> Ellis, *op cit*, 274.

<sup>139</sup> *Ibid*, 288.

<sup>140</sup> Samhat, “International Regimes and the Prospects for Global Democracy,” 182-183 and 186. With Rodger Payne, Samhat acknowledges the criticisms sometimes levelled at NGOs—that they themselves are not democratically accountable and therefore lack popular legitimation—but avers that such problems are being addressed through measures such as codes of conduct. (Samhat and Payne, “Regimes, Public Spheres and Global Democracy,” 285-286.)

Rischarde's GINs would incorporate civil society actors alongside representatives from governments and businesses. The membership of the networks would increase progressively throughout their three phases. During the 'constitutional phase', IGOs would facilitate the selection of a small number of experts, with input from the civic and private sectors.<sup>141</sup> IGOs would in fact take part in GINs as facilitators only, not as problem-solving members. One of their prime roles would be to secure the involvement of poorer states. Rischarde believes IGOs would ensure fair representation and global thinking, because as technocratic organisations they would have "less of an axe to grind" than the sectorally-appointed members (although elsewhere Rischarde deems IGOs unable to avoid the disharmony of international politics, because they are owned and overseen by nation-states).<sup>142</sup> This logic ignores the power relations between strong and weak states identified by Held and UNDP in IGOs.

Rischarde suggests a broadening of the network membership in the 'norm-producing phase', to include "all interested parties." He also puts forward what he terms a "peculiar methodology" for norm generation, to be enshrined in the code of conduct. Firstly, representatives would have to act as "global citizens" rather than ambassadors for their own sectors *per se*, at risk of exclusion should they fail to do so.<sup>143</sup> Secondly, rather than voting, networks would operate by "rough consensus," defined as a sufficient level of agreement on fundamentals to enable norm production. To achieve this consensus, interested parties would take part in 'electronic town meetings' held via the internet, on a "potentially vast" scale (by the 'implementation phase', according to Rischarde, the membership could perhaps run to tens of thousands; Arnd Juergensen questions this

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<sup>141</sup> Rischarde, *op cit*, 172-173 and 179. Benner, Reinicke and Witte emphasise the importance of a transparent selection process, with clear criteria, to the accountability of networks. (Benner, Reinicke and Witte, *op cit*, 203.) The membership selection process that Rischarde lays out seems rather circular, however. He writes, "Each network would start with three facilitators: the global multilateral [IGO] in the lead, one representative selected from the network's civil-society membership, and one representative selected from the business membership. Together they would be in charge of selecting and roping in the first members (a tricky task)." (Rischarde, *op cit*, 172.) Thus the facilitators would be selected (by whom is not clear) from among an already existing membership. Note that the GINs might also decide to set up an independent panel of experts, presumably to work in an advisory capacity. Given that Rischarde deems it necessary for these experts to remain outside the networks in order to safeguard scientific independence, he must consider that their expertise would be of a different order to that of the network members. (*Ibid*, 175.)

<sup>142</sup> *Ibid*, 163, 172 and 188-189.

<sup>143</sup> *Ibid*, 174 and 192. Cleveland observes, from experience, that the transition to an ethos of global citizenship is one that existing committees and commissions have to make if they are to be successful. (Cleveland, *op cit*, 62.)



“inflated” view).<sup>144</sup> The electronic meetings concept is problematic, given that some people have better access to communications technologies than others, as highlighted by Chasek and Rajamani. Despite Rischard’s emphasis on urgency, it might take a significant part of the twenty years he allows for global problem-solving for the internet to become equally available everywhere. Rischard foresees large numbers of knowledgeable, qualified people “chiming in” through the meetings, but does not articulate how their qualifications or interests would be verified, or how all their contributions would be taken on board.<sup>145</sup>

Held has questioned the potential legitimacy of Rischard’s GINs, on the grounds that they would provide no means to effectively arbitrate the range of actors involved.<sup>146</sup> This has implications for the GGI, which would be explicitly based on Rischard’s multisectoral model. Rischard admits that questions of legitimacy and democratic representation within his proposed networks are the “hardest by far.” His first response is simply, “What’s the alternative?” This hardly seems adequate. He goes on to argue that as GINs would not enact legislation and thus act only as “a kind of governance tool” rather than a government, issues of democratic representation would lose cogency. Even so, Rischard envisages the ‘electronic town meetings’ bringing “a greater element of democratic participation than the traditional local-to-global pyramid of electoral processes.”<sup>147</sup> For Rischard, GINs would encapsulate a novel form of legitimacy—“horizontal legitimacy”—because they would cut across borders and sectors. They would complement rather than replace the traditional “vertical legitimacy” of nation-states, pressuring states and their “short-term oriented, territorially minded traditional politicians” into acting accountably and with a longer-term and more global perspective. In this way they would work in a similar fashion to advocacy NGOs, as Rischard acknowledges: “The more the global issues network looks like an activist NGO in that phase, the better.”<sup>148</sup>

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<sup>144</sup> Rischard, 174 and 179. Juergensen deems Rischard’s expectations of the effectiveness of the electronic town meetings somewhat overblown. (Juergensen, “Looking Ahead,” 204.)

<sup>145</sup> Rischard, op cit, 189.

<sup>146</sup> Held, *Global Covenant*, 107.

<sup>147</sup> Rischard, op cit, 189.

<sup>148</sup> Ibid, 177, 182-183 and 186.

Slaughter, like Rischard, is concerned with democratic participation. She purports that 'global deliberative equality' should be the foundational norm of global governance. By this she means that all those individuals affected by common problems should be able to participate in collective deliberation about how to solve them.<sup>149</sup> Their participation would be through representatives, but not the civil society agents identified by Samhat, for Slaughter goes on to articulate this principle exclusively in terms of government networks. Under a "presumption of inclusion," all those government institutions wanting to join a network would be allowed to do so, subject to their meeting certain criteria. (Slaughter suggests that these criteria could include certain levels of economic and political development, which might prove difficult for some states in the South to achieve.)<sup>150</sup>

Slaughter endorses representation through government officials because she believes that, unlike actors from the private sector or civil society, they can be held accountable through political mechanisms. She acknowledges that these officials are often seen as unelected technocrats acting on behalf of vested interests, but suggests ways in which such perceptions could be mitigated; namely, government networks could host common websites, engage systematically with counterpart networks of corporations and civil society organisations and promote enhanced accountability at domestic levels.<sup>151</sup> Whether government officials in genetics and bioethics are seen as legitimate representatives of national interests and to what extent they can be held accountable will be investigated in Chapters 5 and 6.

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<sup>149</sup> Slaughter, *op cit*, 29 and 245-247.

<sup>150</sup> *Ibid*, 246-247. Slaughter's model seems somewhat inconsistent in this regard. She argues that an advantage of 'network norms' would be that they would stipulate criteria for membership specific to the issue at hand, thus avoiding what she sees as a pernicious problem in current international relations, the labelling of whole countries as pariahs on account of the misdemeanours of particular elements within them. Under the constitutional norm of global deliberative equality, any government official or unit able to meet these criteria could not be excluded from the network. Whether or not they could be seen to meet the economic or political development criteria outlined above, however, would depend on several factors and so would not fall within the remit of any one government official or unit. It would also be difficult for the networks to offer "targeted technical assistance" towards the achievement of such broad standards to single government institutions. (*Ibid*, 25 and 246-247.)

<sup>151</sup> *Ibid*, 10, 28-29, 220-221, 235, 259 and 266. Slaughter suggests a "grab-bag" of domestic political solutions, which should augment the accountability of government networks, decided upon by each national polity in response to their perceptions of potential transnational problems. What exactly a "grab-bag" is or would entail is unclear, however, except in the context of the United States. (*Ibid*, 28-29, 241 and 259.)



Slaughter envisages a system in which government officials would be explicitly recognised as having both domestic and international duties.<sup>152</sup>

National officials are responsible to national constituencies for their domestic and...their transgovernmental activities. At the same time...government networks constitute a global governance system, which must somehow be accountable to the global community as a whole, comprising both states and individuals whose collective interests stem from a common humanity.<sup>153</sup>

This stance seems somewhat confused. Slaughter stresses that officials would have two faces, but one audience; that is, they would be accountable for their actions both within and across borders, but only to the national populace: "Dual function thus does not imply dual accountability."<sup>154</sup> Slaughter believes it would be too great a leap for government representatives to see themselves as representing a larger transnational or global constituency (unlike Rischard, who stipulates they must put national interests aside and act as global citizens<sup>155</sup>). She also avows, however, that government officials would need to pay attention to global interests, the priority of which relative to national interests would have to be calculated on a case-by-case basis. Each state would devise guidelines on how this calculation should be made, but these would be subordinate to general (or 'constitutional') norms governing transnational networks, which all nations would come together to form.<sup>156</sup> Peter Berkowitz is highly critical of Slaughter's model on this front, on the grounds that it pays insufficient attention to self-interest as a salient feature of networking.<sup>157</sup>

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<sup>152</sup> Ibid, 28-29.

<sup>153</sup> Ibid, 218.

<sup>154</sup> Ibid, 232. Kenneth Anderson makes a similar point concerning Slaughter's confusing vision. On her statement that dual function does not imply dual accountability, he comments that this does not chime with her assertions that government officials should have global responsibilities and be subject to international agreements on an individual basis. On her solution (namely that officials should think in terms of both national and global interests and prioritise between these according to the issue at hand, as outlined above), he writes, "How this is not an explicit statement of dual allegiance, dual loyalty, and dual accountability is, frankly, unfathomable." Anderson also doubts that "ordinary voters" (Slaughter, op cit, 259) could adequately monitor government networks. (Anderson, "Squaring the Circle?" 1295 and 1296.)

<sup>155</sup> Rischard, op cit, 174.

<sup>156</sup> Slaughter, op cit, 233-235 and 243-244.

<sup>157</sup> Berkowitz writes, "So little attention does she [Slaughter] give to self-interest in politics that she seems never to factor into her account of the new world order certain salient features, comical as well as unlovely, of her central concept. In fact, 'networking' also includes the posturing, posing, and preening for position; the creation of rigid hierarchies and exclusive cliques; and the lust for power that hides behind high-minded formulations and manipulates sound principles for personal and party advantage." (Berkowitz, "Laws of Nations," 79.) Vlad Perju also comments that Slaughter's vision may not be enough to ensure the just world order for which she is aiming. (Perju, "Comparative Constitutionalism and the Making of A New World Order," 466.)



Held and Archibugi advocate that individuals should be entitled to take part in policy formation at the global level, as fully-fledged cosmopolitan citizens rather than through government representatives. Which individuals and groups might come together to hold to account relevant parties over a certain issue would be dictated less by geographical proximity than by whether they fell within, to use one of Held's recurring phrases, "overlapping communities of fate."<sup>158</sup> Borrowing again from UNDP's work on GPGs, Held determines that "those who are significantly affected by a global good or bad should have a say in its provision."<sup>159</sup> Archibugi similarly states that "cross-border issues" should be dealt with under a democratic principle that "everyone affected is able to take part in the decision-making."<sup>160</sup> Held defines three categories of impact: strong, where vital needs or interests are affected, with consequences for life expectancy; moderate, where people's abilities to participate in economic, cultural and political activities are affected, with consequences for life chances; and weak, where lifestyle or consumption choices are affected, which could lead to frustration, tension and conflict. Being weakly affected by a good or bad would not be enough to place someone in the relevant community of fate, because this would make the community so large as to render cosmopolitan citizenship impracticable. Held concludes that those who are strongly and moderately affected by an issue should be involved in the decision-making and regulation surrounding it, either directly or indirectly. Where this does not happen there is an accountability gap.<sup>161</sup>

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<sup>158</sup> Held, *Global Covenant*, 173-174; Archibugi, "Principles of Cosmopolitan Democracy," 204-205 and 211-112. On a note of caution, Held observes that globalisation has not been mirrored by a growing sense of global citizenship and that people's loyalties and identities are still rooted first and foremost at local, subregional or national levels. (Held, "From Executive to Cosmopolitan Multilateralism," 166.) Nadia Urbinati criticises the cosmopolitan democracy project on the grounds that it is unclear how national citizens would overcome their nation-based interests when voting at global level. (Urbinati, "Can Cosmopolitical Democracy Be Democratic?" 79.) Similarly, Slaughter and Thomas Hale predict that nationalism is not going to disappear in the near future, thus it must be harnessed to contribute to cosmopolitan ideals. Unsurprisingly, they suggest that trans-governmental networks may offer a means to do this. (Slaughter and Hale, "A Covenant to Make Global Governance Work," 129-131. This commentary forms a chapter in the book *Debating Globalization*, which comprises an essay by David Held ("Globalisation: The Dangers and the Answers," itself a shortened version of *Global Covenant*) and a series of responses, most of which originally appeared on [www.openDemocracy.net](http://www.openDemocracy.net).)

<sup>159</sup> Held, *Global Covenant*, 97. UNDP resurrects the "forgotten principle of equivalence," which suggests that "it is desirable to align as much as possible the structure of political decisionmaking (particularly different levels of geographic jurisdiction) with the range and type of a good's spillover effects." (Kaul *et al*, "How to Improve the Provision of Global Public Goods," 27-28.)

<sup>160</sup> Archibugi, "Cosmopolitan Democracy and its Critics," 443-444.

<sup>161</sup> Held, *Global Covenant*, 99-100 and "Democratic Accountability and Political Effectiveness," 383.



Under cosmopolitan democracy new forms of accountability would complement those afforded by democratic elections.<sup>162</sup> A full-blown cosmopolitan polity would involve an “overarching network of democratic public fora,”<sup>163</sup> whereby people would be members of several different communities according to the issues affecting them and would be able to engage politically in those issues in a variety of ways. These would include forms of both direct (local) and representative (global) democracy, but also novel democratic arenas such as stakeholder consultations (that is, direct involvement of representatives of major groupings) and collective views arrived at through impartial deliberative examination of opinion and informed participation (if indeed impartiality of opinion and information can ever be guaranteed).<sup>164</sup> With genomics designated the ‘heritage of humanity’ and a global public good, who should take part in such fora, if established for genetics and bioethics, would have to be determined.

### **3.5.3 Norms, implementation and enforcement**

Both UNESCO and those at TJCB have a stated purpose to set out universal norms on genetics and bioethics. The nature and content of these norms will affect how they are implemented and enforced and thus are key to the efficacy of the UNESCO declarations and the proposed GGI. In a world of sovereign states, governance mechanisms are ultimately self-regulatory, relying heavily on the perceived threat of reciprocal action and national concerns with status and reputation.<sup>165</sup> Ellis describes this state of affairs succinctly: “States are both subjects and instruments of international law, being both the addressees of international norms and the agents responsible for their domestic implementation and enforcement.”<sup>166</sup> The different approaches to governance—regimes, networked governance and cosmopolitan democracy—seek to address this conundrum in

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<sup>162</sup> Keohane, “Global Governance and Democratic Accountability,” 137 and 140.

<sup>163</sup> Held, *Global Covenant*, 109.

<sup>164</sup> Held, “From Executive to Cosmopolitan Multilateralism,” 175-176.

<sup>165</sup> Vogler, *op cit*, 41.

<sup>166</sup> Ellis, *op cit*, 292.

various ways, accommodating sovereignty through soft and hard forms of power or, more radically, challenging its very essence.

Young describes the conception and revision of regimes as “messy processes.” Norms are often drafted ambiguously rather than to “coherent institutional designs,” representing compromise positions reached through hard bargaining combined with decision-making by consensus.<sup>167</sup> Negotiations aimed at binding accords, in particular, sometimes suffer a ‘lowest common denominator’ effect. Non-binding instruments, which allow for fluctuating levels of compliance and are thus less threatening to reluctant states, may therefore be preferred.<sup>168</sup> The corresponding disadvantage lies in their modest enforcement power, which is seen to render them weaker than binding agreements. This “conventional wisdom” is challenged by David Victor *et al* in their study of international environmental regimes.<sup>169</sup> Binding instruments that set low standards, even if fully complied with, may have negligible impact on a given problem. By contrast, non-binding agreements enshrining high standards, even if only aimed towards, may effect significant behavioural change.<sup>170</sup> Among states, peer pressure may induce conformity over time. In a review of different approaches to regime theory, Baldev Nayar describes this process:

In an interdependent world where elites are compelled to interact repeatedly, the institutionalists [neoliberals] maintain, social practices or regularized patterns of behavior develop. As these persist, they acquire a normative aura and come to act as constraints on the behavior of leaders. As Oran Young puts it, “In the typical case, international institutions are extremely difficult to get rid of.”<sup>171</sup>

One way to encourage adoption of regimes at national level may be through systems of implementation review (SIRs). According to Victor *et al*, SIRs enhance transparency and accountability and lessen the chance of non-binding commitments being ignored.<sup>172</sup>

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<sup>167</sup> Young, *Governance in World Affairs*, 47 and 103.

<sup>168</sup> Stokke, “Regimes as Governance Systems,” 50.

<sup>169</sup> Victor, Raustiala and Skolnikoff introduce fourteen case studies, conducted through the International Institute for Applied Systems Analysis, in their edited volume, *The Implementation and Effectiveness of International Environmental Commitments*.

<sup>170</sup> Victor, Raustiala and Skolnikoff, “Introduction and Overview,” 7; Raustiala and Victor, “Conclusions,” 685 and 705.

<sup>171</sup> Nayar, “Regimes, Power, and International Aviation,” 142-143. (Nayar quotes Young, *International Cooperation*, 64.)

<sup>172</sup> Victor, Raustiala and Skolnikoff, “Introduction and Overview,” 18.



Young similarly remarks, “Well-constructed SIRs are important in almost every case as methods of retaining the attention of policymakers and avoiding the onset of ‘out of sight, out of mind’ syndrome.”<sup>173</sup> Victor *et al* note that poor data reporting is a chronic problem, however, in terms of both quantity and quality. They also identify two further trends. Firstly, active and effective implementation review often evolves informally, after an agreement has entered into force. Secondly, states are becoming more open even to external review, in the interests of international cooperation. Whether the UNESCO declarations follow any of these trends will be explored in Chapter 6.<sup>174</sup>

Where norms are not being upheld by member states, IGOs have two approaches to encouraging implementation: enforcement and management.<sup>175</sup> Which is deemed appropriate will depend on whether non-compliance is attributed to self-interested choice or incapacity.<sup>176</sup> Vogler writes, “They [governments] may simply lack the technical personnel and data gathering facilities to fulfil their obligations under a regime.”<sup>177</sup> Young judges IGOs to be “notoriously weak” in applying enforcement measures such as sanctions and thus considers initiatives like UNESCO’s capacity building activities, aimed at strengthening those desiring to comply, a better option in many cases.<sup>178</sup> Victor *et al* found that a combined approach can prove effective; the threatened withdrawal of managerial assistance, for example, might be a powerful enforcement tool. The likely success of either or both methods will depend partly on a system’s capacity to apply them.<sup>179</sup> Young notes that organisations administering regimes often struggle for sufficient material resources, especially for programmes aimed at developing countries.<sup>180</sup>

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<sup>173</sup> Young, *Governance in World Affairs*, 119.

<sup>174</sup> Victor, Raustiala and Skolnikoff, “Introduction and Overview,” 18; Raustiala and Victor, “Conclusions,” 677-678, 680 and 695.

<sup>175</sup> An oft-cited work on the management approach (and, according to Young, the most comprehensive) is that of Abram and Antonia Chayes: *The New Sovereignty: Compliance with International Regulatory Agreements* (Cambridge, Massachusetts: Harvard University Press, 1995). (Young, *Governance in World Affairs*, 96.)

<sup>176</sup> Raustiala and Victor, “Conclusions,” 681.

<sup>177</sup> Vogler, *op cit*, 169-170.

<sup>178</sup> Young, *Governance in World Affairs*, 81, 95-96 and 100.

<sup>179</sup> Raustiala and Victor, “Conclusions,” 683-684.

<sup>180</sup> Young, *Governance in World Affairs*, 119.

Whether a regime is adopted at national level and, if so, how successfully, may be as dependent on internal dynamics and pressures as on IGO enforcement or management mechanisms. Where international arrangements disrupt or are incompatible with local procedures, their efficacy may be impaired.<sup>181</sup> This is particularly pertinent to bioethics, given the debate between universalism and pluralism highlighted at 2.1.2.1. Which government agency takes on responsibility for implementing a regime may also be a key factor. Echoing Slaughter's disaggregated state, Young observes, "Regimes ordinarily become the property of specific public agencies within governments rather than of the government as a whole." Thus it is essential for IGOs to identify and liaise with the most appropriate national bodies.<sup>182</sup> Young sees unofficial groups as of "even greater importance," however. Where regimes trigger active communities willing to give time and energy to their fulfilment, they cannot be shunted aside through "benign neglect."<sup>183</sup> It might be expected that involving relevant constituencies in negotiations would harness their subsequent support, but this does not necessarily follow. Victor *et al* found that including "implementation expertise" in decision-making led to better-crafted agreements, but had little impact in terms of encouraging participation in their realisation.<sup>184</sup>

Sceptical of current systems for inducing adherence to international norms and principles, Rischard, Slaughter and Held suggest alternatives. These range from variations on the enforcement and management approaches to regimes to new understandings of sovereignty. Rischard's networks would engender "reputational effects" in their implementation phase. In conjunction with the adjoined 'electronic town meeting', each GIN would become a "rating vehicle," monitoring the compliance of states and other stakeholders with the norms and standards developed in the previous phase. The norms might be general, applying to all stakeholders in the issue at hand, or sector specific. Some would be intended to guide nation-states as to what legislation they should pass, perhaps encompassing existing treaties; others would address IGOs, with regard to

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<sup>181</sup> Ibid, 122-123.

<sup>182</sup> Ibid, 48 and 94.

<sup>183</sup> Ibid, 94-95 and 105.

<sup>184</sup> Raustiala and Victor, "Conclusions," 665.



financing or “even sometimes telling them how to get their act together with respect to the issue at hand.”<sup>185</sup> Whether IGOs would be inclined to listen to GINs acting in this rather dictatorial fashion is questionable, especially considering that they would have been deliberately left out of the ‘norm-producing phase’. The GGI might face a similar problem in setting itself up as overall coordinator of all existing genetics initiatives.<sup>186</sup>

Rischarde recognises that norms are often referred to as ‘soft law’<sup>187</sup> and that the networks would have neither legislative power nor regulatory authority, but nevertheless deems the proposed networks “anything but soft,” as they would have the moral authority to name and shame “rogue players.”<sup>188</sup> He writes, “Global issues networks... are hard in that they will use the sledgehammer of ratings and reputational effects—much more potent devices than even rules or sanctions.”<sup>189</sup> Whether reputational effects are in fact this potent and, if so, under what circumstances will be explored in Chapter 7. One possible limitation is their dependence on renegade actors being susceptible to a burden of shame. Held has drawn attention to this weakness in regard to Rischarde’s proposals, stating that GINs would “contribute little to the question of norm and rule enforcement in the face of a reluctant actor.”<sup>190</sup> Malcolm Scully has likewise commented that ‘naming-and-shaming’ would be unlikely to have much effect on unilateralist states.<sup>191</sup>

Despite predicting that GINs would wield a ‘hard’ power more effective than that of IGOs, Rischarde acknowledges that they would be ultimately reliant on these more traditional

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<sup>185</sup> Rischarde, *op cit*, 176-177.

<sup>186</sup> Dowdeswell *et al*, *op cit*, 139.

<sup>187</sup> ‘Soft law’ essentially refers to legally non-binding norms, although where the formal distinction between hard and soft law lies (or indeed whether it is possible to distinguish one) is contested among scholars of international law. (See Shelton, “Introduction: Law, Non-Law and the Problem of ‘Soft Law’” and Chinkin, “Normative Development in the International Legal System.”)

<sup>188</sup> Rischarde, *op cit*, 177-178. Rischarde suggests that GINs could co-opt the media in this endeavour and gives the Indonesian government’s five-tier ranking system of the environmental credentials of businesses as an example of a successful ‘naming-and-shaming’ mechanism. This system applauds those at the top, while giving those at the bottom six months to improve before being publicly named. (*Ibid*, 178.)

<sup>189</sup> *Ibid*, 185.

<sup>190</sup> Held, *Global Covenant*, 107.

<sup>191</sup> Scully, “A Network of Global Solutions,” B13. Benner, Reinicke and Witte use similar terminology to Rischarde in writing about “naming and shaming” and “public reputational accountability” in the context of global policy networks. They are concerned with the reputations and accountability of the networks themselves, however, rather than those at whom the networks would target their norms. They also acknowledge that naming and shaming would have little effect on “rogue actors,” but aver that such actors would be unlikely to join the networks in the first place. (Benner, Reinicke and Witte, *op cit*, 199-200.)

bodies and on nation-states, because “governance needs government.” The reasons for this are threefold: firstly, GINs would be materially dependent on IGOs for their launch events and subsequent funding; secondly, the norms would need to be effected in national law; and thirdly, there would be no time to set up new institutions.<sup>192</sup> Slaughter’s government networks, both horizontal and vertical, would mirror Rischard’s GINs in that the norms developed would have no legal force unless implemented at domestic level. Horizontal networks would employ soft power on a continuum, running from information to socialisation to persuasion to discussion and debate, to foster national level adherence.<sup>193</sup> Vertical networks would see international organisations directly marshalling the legislative, regulatory or judicial power of their domestic counterparts in order to achieve maximum efficacy. “Absent a world government,” writes Slaughter, “it is impossible to grant supranational officials genuine coercive power.”<sup>194</sup>

To promote implementation, costs and prestige would be attached to failing or meeting respectively a network’s norms and standards. To this end, Slaughter introduces a new conception of sovereignty: disaggregated sovereignty. At present, she avers, there is a “conceptual blind spot” in international law and politics, whereby separate government institutions are not formally recognised independently of the unitary state. To address the myopia, Slaughter suggests that these institutions should individually bear the rights and responsibilities of sovereignty. Each would have a discrete mandate to meet international legal obligations (which would perhaps lead to duplication and confusion should institutions with overlapping responsibilities apply these instruments contradictorily at national level). Sovereignty would be newly understood in terms of capacity to take part in transgovernmental networks.<sup>195</sup> Like those of the management school of regime theory,

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<sup>192</sup> Rischard, op cit, 185.

<sup>193</sup> Slaughter, op cit, 27, 215 and 263. Soft power is a term coined by Joseph Nye, Jr. He writes, “What is soft power? It is the ability to get what you want through attraction rather than coercion or payments. It arises from the attractiveness of a country’s culture, political ideals, and policies. When our [the United States’] policies are seen as legitimate in the eyes of others, our soft power is enhanced... When you can get others to admire your ideals and to want what you want, you do not have to spend as much on sticks and carrots to move them in your direction.” (Nye, *Soft Power*, x.)

<sup>194</sup> Slaughter, op cit, 13-14 and 20.

<sup>195</sup> Ibid, 25, 33-34, 266 and 268-269. This new notion of sovereignty has been criticised by Berkowitz and Anderson. Berkowitz writes, “One should not underestimate the radicalism of Slaughter’s proposal, encapsulated in her casual exercise in redefinition—as if one could disguise the rejection of a fundamental



Slaughter sees compliance with international norms as being as much about capacity as willingness. She particularly cites developing countries as lacking this capacity and suggests that government networks could provide technical assistance in helping them to build it. This would represent power employed in a positive form, unlike Rischard's largely negative 'naming-and-shaming'.<sup>196</sup>

Like Slaughter's government networks, cosmopolitan democracy would entail a new understanding of sovereignty. Where traditionally states have been protected from external accountability by the national sovereignty principle,<sup>197</sup> Held and Archibugi argue that allowing them to act with impunity simply because they sit within certain borders is incompatible with democracy. Hence states should not be considered to be "ontologically privileged."<sup>198</sup> The two theorists frame their proposed alternatives differently. Held perceives a "liberal international sovereignty" to be already emerging in the international arena. Under cosmopolitan democracy, this would entrench powers and constraints, rights and duties that might sometimes conflict with national laws. States would thus forfeit their right to sovereignty if they violated standards of international order, understood in terms of human rights and democracy.<sup>199</sup> Archibugi endorses a similar ethos, but argues that the canon of sovereignty should be supplanted by that of "global constitutionalism."<sup>200</sup>

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principle by keeping the name while changing the meaning." (Berkowitz, op cit, 75.) Anderson likewise comments that Slaughter's argument "operates by pure definitional fiat," such that she has "redefined sovereignty to mean engaging in activities characteristic of giving up traditional sovereignty." He believes she has confused sovereign power with the international benefits it can be used to secure. (Anderson, op cit, 1299-1300.)

<sup>196</sup> Slaughter, op cit, 4, 26 and 261. Slaughter draws on the work of Chayes and Chayes, as does Allyn Taylor in a 1999 article suggesting that the UNESCO declaration on the human genome (UDHGHR) requires a stronger supervisory mechanism to encourage compliance. Taylor notes that any such mechanism would have to be administered in a positive manner: "Procedures must be instituted to ensure that a truly constructive dialogue is established rather than a combative and coercive confrontation." (Ibid, 185; Taylor, "Globalization and Biotechnology," 535-536. Slaughter and Taylor refer to "On Compliance," *International Organization* 47 (2) (1993), 175-205 and *The New Sovereignty*.) Rischard does suggest a positive function for the 'electronic town meetings', in that they could become vehicles for best practice and knowledge exchange, but by far the greater part of his description of the 'implementation phase' is devoted to the 'naming-and-shaming' concept. (Rischard, op cit, 178.)

<sup>197</sup> Keohane, "Global Governance and Democratic Accountability," 147 and 149.

<sup>198</sup> Archibugi, "Cosmopolitan Democracy and its Critics," 452; Held, "From Executive to Cosmopolitan Multilateralism," 168.

<sup>199</sup> Held, *Global Covenant*, 119 and 131.

<sup>200</sup> Archibugi, "Cosmopolitan Democracy and its Critics," 452 and "Demos and Cosmopolis," 35.

Held stresses that cosmopolitan democracy would not necessitate a diminution of state power and capacity *per se*.<sup>201</sup> It is difficult to envisage how it would be possible to have effective supranational levels of governance without affecting state sovereignty, however. For regional and global bodies to have any authority, states would have to concede a degree of autonomy. At present, states can assert that international norms to which they would rather not adhere lack democratic legitimisation, a claim that would be invalid under cosmopolitan democracy.<sup>202</sup> Held does not specify how powerful states would be won over to innovations such as regional parliaments or an assembly legitimised for direct intervention. In its present form, the UN struggles to persuade states to uphold international law, both in spite and because of their ultimate sovereignty. To convince states to give up this sovereignty would be a task more difficult by an order of magnitude.<sup>203</sup> Such considerations are essential to effective genetics and bioethics governance. The combination of non-binding agreements and state sovereignty does not augur well for the implementation of the norms and principles of the UNESCO declarations and the proposed GGI. At issue is whether efficacy would be more realistically achieved by changing the nature of sovereignty or by finding ways to govern in spite of it.

### 3.5.4 The location of governance

Intrinsic to the issues explored in 3.5.2 and 3.5.3—representation, legitimacy, accountability, norms, implementation and enforcement—is the location of governance. This informs how constituencies are defined, who represents them and at what levels norms are upheld. With regard to genetics and bioethics, whether governance is best

<sup>201</sup> Held, "From Executive to Cosmopolitan Multilateralism," 179-180.

<sup>202</sup> *Ibid.*

<sup>203</sup> Several theorists have made similar critiques of cosmopolitan democracy. Adam Lupel writes, "States, as the major actors in the international arena, have a strong interest in maintaining their *de jure* sovereignty; sovereign status remains the foundation of state identity and agency in the international arena. This is never to be given up lightly." (Lupel, "Tasks of a Global Civil Society," 122.) David Chandler and Slaughter and Hale are sceptical about how realistic Held's proposals are and Martin Wolf and Meghnad Desai, two of the contributors to *Debating Globalization*, criticise what they see as Held's benign view of sovereignty. (Chandler, "New Rights for Old?" 339 and 343; Slaughter and Hale, *op cit*, 128; Wolf, "The Case for Optimism," 41; Desai, "Social Democracy as World Panacea?" 68-69.)



located at local, national, regional, international or multiple layers and how far norms should be applied universally must therefore be interrogated. The traditionally state-centric approach of regime theory is broadened in the normative work of Young, Samhat and Ellis. As seen in the previous section, Young detects a vital role for both state and non-state actors at national level in the implementation of regimes. Samhat appears to separate the decision-making and implementation sides of governance in terms of location. He writes, "The international regime, characterized as a global public sphere, provides a space for the practice of democracy above the state." Both he and Ellis recognise, however, that "strong states" are needed to administer whatever rules and norms are agreed upon.<sup>204</sup>

Rischar, Slaughter and Archibugi reject global government as an option, on the grounds that a single centralised institution would be too distant from too diverse a populace and would hold a dangerously concentrated form of power.<sup>205</sup> They differ in where they locate the optimum level of governance within their models, however. Rischar's networks, by definition, would operate at global level, but would circumvent actual and metaphorical distances between people by creating "virtual public space" (through the 'electronic town meetings') around specific issues.<sup>206</sup> In contrast, Slaughter's government networks would employ a 'constitutional norm' of subsidiarity and thus locate governance at the lowest level possible, defined as "that closest to the individuals and groups affected by the rules and decisions adopted and enforced." What this level might be—from local to national to regional to global—would depend on "practicability."<sup>207</sup> Cosmopolitan democracy would also enshrine subsidiarity, under the single principle of 'inclusiveness and subsidiarity'. This dictates that decision-making should as far as possible be decentralised, to afford

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<sup>204</sup> Samhat, "International Regimes and the Prospects for Global Democracy," 179-180 and 189; Ellis, *op cit*, 280.

<sup>205</sup> Rischar, *op cit*, 165-167; Slaughter, *op cit*, 8; Archibugi, "Cosmopolitan Democracy and its Critics," 454. Marchetti, in advocating his vision of world federalism or "cosmo-federalism" (that is, a democratic union of states, consisting of a directly elected law-making assembly and federal government), argues that the dangers of homogeneity and tyranny would actually be higher without a federal authority, which would respect local differences and allow citizens to express dissent through elections. (Marchetti, *op cit*, 287 and 300-301.) van den Anker, although an advocate of global governance over global government, makes a similar comment in terms of the danger of the former if procedures of influence are not transparent and there are no formal rules for including the powerless in decision-making. (van den Anker, *op cit*, 283.)

<sup>206</sup> Rischar, *op cit*, 182.

<sup>207</sup> Slaughter, *op cit*, 30.



people maximum opportunity to influence the social conditions that shape their lives.

Democracy should therefore be centralised solely for those issues where life expectancies and life chances can be effectively safeguarded only at transnational levels.<sup>208</sup>

The principle of subsidiarity notwithstanding, Slaughter, Held and Archibugi embrace multilayered governance, but in different ways. Slaughter envisages a global lattice of horizontal and vertical government networks. Horizontal networks would be the more common: "Even on a global scale, the vast majority of governance tasks should still be taken by national government officials." According to Slaughter, this would ensure "bottom up" global governance<sup>209</sup>; whether government officials are truly representative of the grassroots is highly questionable, however. Held and Archibugi recommend the involvement of a greater diversity of actors and types of association (as shown in 3.5.1 and 3.5.2.) Under cosmopolitan democracy, regional and global fora would complement those at local and national levels.<sup>210</sup> Held outlines the need for a multilayered approach as follows:

Today, if people are to be free and equal in the determination of the conditions that shape their lives, there must be an array of fora, from the city to global associations, in which they can hold decision-makers to account. If many contemporary forms of power are to become accountable and if many of the complex issues that affect us all—locally, nationally, regionally and globally—are to be democratically regulated, people will have to have access to, and membership in, diverse political communities.<sup>211</sup>

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<sup>208</sup> Held, *Global Covenant*, 100 and 107-108. van den Anker criticises Held for failing to articulate the mechanisms by which democracy at the local level would be ensured: "The model of cosmopolitan democracy includes local participation in its aims but does this at the level of specification of the principles of levels of governing instead of taking it into account in the model for global democracy." He cites alternative models such as deliberative democracy and the civil society networking approach as promising in this regard. (van den Anker, op cit, 282-284.)

<sup>209</sup> Slaughter, op cit, 15-16 and 256-257.

<sup>210</sup> Held, "From Executive to Cosmopolitan Multilateralism," 176-179; Archibugi, "Principles of Cosmopolitan Democracy," 199 and 209.

<sup>211</sup> Held, *Global Covenant*, 115. As stated earlier, Held acknowledges that the particular layer of governance most appropriate for a given issue will not be obvious or natural. Several commentators reflect on this. James Bohman labels the potential conflicts between different democratic units the "demoi problem" and raises the question of how the general framework for cosmopolitan democracy will be decided upon democratically. (Bohman, "From *Demos* to *Demoi*," 298 and 303-304.) In similar fashion, Lupel describes the cosmopolitan democratic order as "complex and burdensome." Lupel, op cit, 119.) Marchetti sees world federalism as the answer to the problems of this "fuzzy net of global governance," which would provide through increased political participation a central authority to "determine the allocation of competencies and responsibilities in any specified issue area." (Marchetti, op cit, 296-297.) Urbinati reaches an opposite conclusion. Identifying a "spaceless democracy" as carrying an "anti-democratic risk," she objects to decision-making procedures that are "actually the province of states" being assigned to the global level. (Urbinati, op cit, 67 and 68.)



As on the location of governance, so do Samhat, Rischard, Slaughter and Held and Archibugi differ in their views on universalism versus pluralism. Rischard endorses universal values for his inherently global model, albeit of a particular kind: "The network must make a constant appeal to universal values, not just in the broad sense in which the philosopher Kant meant it but in terms of the more specific values that are a prerequisite to the solution of the global issue at hand."<sup>212</sup> Where Rischard appeals to universal values, Slaughter endorses pluralism, under the constitutional norms of 'legitimate difference' and 'checks and balances'. Legitimate difference would restrain government networks from attempting to cover over differences in fundamental values. Instead, they would draw up compilations of best practices, for regulators to adapt to local circumstances. Similarly, checks and balances—between the different disaggregated units horizontally and vertically—would enshrine "an affirmative norm of friction and constructive ambiguity."<sup>213</sup> These pluralistic norms would contrast directly with the third principle of cosmopolitanism, which states that rules and principles must be universally and impartially shared; those that cannot be must be rejected. Held gives broad examples of what such rules might comprise, in terms of avoiding harm and meeting urgent needs. He acknowledges, however, that how these should be interpreted could not be specified "once and for all," but would depend on temporally determined cultures and traditions.<sup>214</sup> Samhat takes a balanced approach, seeing regimes as a means to resolve tension between universalism (or solidarism<sup>215</sup>) and pluralism within the international system, on an issue by issue basis. Within regimes, progress is generally incremental in this regard, as norms and principles stemming from initially different perspectives are scrutinised and revised.<sup>216</sup> As reiterated above, bioethics is one area in which the dichotomy between universalism and pluralism is hotly contested. To what degree the UNESCO declarations bridge this divide is thus worthy of consideration.

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<sup>212</sup> Rischard, op cit, 174.

<sup>213</sup> Slaughter, op cit, 31-32, 249-250, 254 and 255. Whether ambiguity is in fact constructive can be questioned. It might lead to confusion and hence either overlaps or gaps in governance. It may be, however, that a debate over the relative authority of different sets of norms would constitute a check (if not a standstill). Slaughter hints at this pay-off, opining that relations among members of government networks should reflect "a system of shared and separated powers designed more for liberty than efficiency." (Ibid, 254.)

<sup>214</sup> Held, "From Executive to Cosmopolitan Multilateralism," 169 and 170-171.

<sup>215</sup> Samhat uses the term 'solidarism', defined as consensus on the moral standards states must uphold. (Samhat, "International Regimes and the Prospects for Democracy," 187.)

<sup>216</sup> Ibid, 188.

### 3.5.5 Time and speed

As Chapter 2 elucidated, the UNESCO declarations and the GGI plans have transpired partly because their parent bodies identified an urgent need for governance at a global level in the fast-developing arenas of genetics and bioethics. Any potential improvements to these governance mechanisms, actual or proposed, must be balanced with the time it would take to introduce them. Samhat, Rischard, Slaughter and Held and Archibugi differ in how long they see it taking their choice of governance system to become effective. For Rischard, time is of the essence. He rejects the traditional tools of global problem-solving on the grounds that international agreements such as treaties and conventions are negotiated through “ritualistic methods” and at a “glacial pace.” He believes GINs would foster “political energy and urgency” and thus pressure existing mechanisms of global governance into faster action.<sup>217</sup> This emphasis on rapidity does not take into account that some of the advantages of international cooperation take time to be realised. Intergovernmental regimes, for example, confer a degree of stability in international relations by allowing reciprocal expectations and mutual information networks to develop. Liberal regime theorists hold that states will enter into multilateral agreements on the understanding that it will be to their long-term advantage.<sup>218</sup> The longer parties remain in a regime, the more interconnected they become and the harder it is to withdraw. “Even though it might formally seem as if treaty regimes have no real power over member states,” writes Goodin, “the informal reality is that they typically provide an awful lot of leverage.”<sup>219</sup>

Rischard's networks would maximise speed by employing norms and reputational effects, which could operate in a “faster space” than more traditional treaties and conventions. Rischard allows one year to set up a network, followed by two to three years for norm production and ten years or more for implementation.<sup>220</sup> It should be noted, however, that

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<sup>217</sup> Rischard, *op cit*, 157 and 181.

<sup>218</sup> Smouts, “Some Thoughts on International Organizations and Theories of Regulation,” 445 and 447.

<sup>219</sup> Goodin, *op cit*, 82.

<sup>220</sup> Rischard, *op cit*, 170, 172, 173 and 177.



his suggestions were first published in 2001<sup>221</sup>; although the GINs may act quickly once established, reaching this stage appears to be a relatively slow process, as seven of the twenty years allocated for the solving of global problems have already passed.

Furthermore, paying heed to the tens of thousands of predicted participants in the 'electronic town meetings' would surely demand an extraordinary amount of time and resources.

As shown in 3.5.1, Slaughter views government networks as potentially flexible and fast instruments of global governance.<sup>222</sup> She recognises, however, that network effects take time to develop. She believes discussion and argument are the key to creative, legitimate and high quality solutions to complex problems and that if the positive nature of conflict could be harnessed in this way the result would be long-term, trusting relationships.<sup>223</sup> Whether UNESCO and the GGI have been party to such discussions will be examined in Chapters 5 and 6. Slaughter also acknowledges that it would take time for the *zeitgeist* to change such that government officials would learn to honour both their national and global constituencies.<sup>224</sup>

Both Nadia Urbinati and Molly Cochran describe the cosmopolitan democracy project as a "top-down" strategy<sup>225</sup>; Slaughter refers to those with a top-down view of global governance as "global dreamers."<sup>226</sup> The project is indeed considered somewhat utopian by certain theorists, including Samhat. Noting that "the long run is a long time," he sees representation through civil society within international regimes as "vital to the realization of global democracy *in the present*." Thus regimes are a "practical or pragmatic means" by

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<sup>221</sup> See note 38.

<sup>222</sup> Slaughter, op cit, 11, 161 and 264.

<sup>223</sup> Ibid, 27 and 214. This view is criticised by Perju, who describes Slaughter's plans for high quality dialogue as "romanticized." In reality, he avers, power relations do not get "filtered out." He also objects to the dialogue and discussion approach on the grounds that it can represent a subtle means for strong states to dominate weak ones: "The current global conversation is far less global than we should expect it to be." (Perju, op cit, 475 and 480.)

<sup>224</sup> Slaughter, op cit, 270.

<sup>225</sup> Urbinati, op cit, 74-75; Cochran, "A Democratic Critique of Cosmopolitan Democracy," 543.

<sup>226</sup> Slaughter, op cit, 256-257.

which cosmopolitan democracy may be realised.<sup>227</sup> Held and Archibugi recognise that the project is not immediately implementable as a *fait accompli*. It would likely be achieved through many “little steps forward,” writes Archibugi, rather than a one-off, momentous shift, with campaigns pursuing limited objectives eventually leading to the desired world order.<sup>228</sup>

Where Slaughter, Held and Archibugi accept, then, that their visions for global governance would take time to be enacted, Rischard views this as time the world does not have. Perhaps his GINs, like Samhat’s regimes as public spheres, could be an interim stage on the path to effective global governance, going some way towards mitigating urgent global needs. Indeed, Held writes of Rischard’s networks, “It is helpful to think of GINs as a useful short-term mechanism in the creation and extension of an enlightened multilateralism, but as an insufficient mechanism alone to reshape global governance.”<sup>229</sup> Slaughter’s government networks might also find a place in a fully realised cosmopolitan democracy, as Held includes “global networks” within his vision of political order, alongside cities, nations and regions.<sup>230</sup>

### 3.6 APPLICATION TO UNESCO AND THE GGI

The previous sections have presented a broad theoretical framework—four approaches across five themes—for thinking about global governance. In Chapters 5 to 7 the analysis turns to the governance of genetics and bioethics and, more precisely, the actual and potential efficacy or otherwise of the UNESCO declarations and the proposed GGI, particularly in developing countries. This analysis will be anchored in the questions laid out here, which ask how far the two mechanisms correlate with explanatory approaches to

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<sup>227</sup> Samhat, “International Regimes as a Pragmatic Institutional Form,” 2, 3 and 31 and “International Regimes and the Prospects for Global Democracy,” 186.

<sup>228</sup> Held, *Global Covenant*, 107; Archibugi, “Cosmopolitan Democracy and its Critics,” 465-466.

<sup>229</sup> Held, *Global Covenant*, 107.

<sup>230</sup> *Ibid*, 113.



global governance and normative suggestions for its improvement, in terms of decision-making and implementation.

The UNESCO declarations, as a set of principles and norms on genetics and bioethics decided upon according to certain rules and procedures, constitute an international regime. It can therefore be asked, to what extent do they reflect or shape the power, interests and values of states and other stakeholders? Like many international agreements, the declarations are housed in an IGO. Held has identified two crises of legitimacy currently faced by these organisations: unequal power between developed and developing countries and long chains of delegation from international to national levels. Chapter 5 will explore whether his assessment can be applied to UNESCO in the context of the genetics and bioethics declarations, in terms of how far power differentials were mitigated by procedural norms on the right to speak, for example, if negotiation sessions bore out UNDP's findings about disparities in delegation size, expertise and preparedness. It will also consider whether TJCB's efforts to date to establish the GGI augur well for its planned leadership from the South.

On chains of delegation, Chapter 5 will investigate whether these exist, in perception or fact, between UNESCO, member states and other stakeholders in genetics and bioethics. Has UNESCO fulfilled the democratic potential of IGOs by including civil society actors, as Samhat might expect? Has it been able to engage with the appropriate national bodies? Have government appointed officials adequately represented their constituents, thus garnering the legitimacy Slaughter believes them to carry? Or have geneticists, ethicists and relevant interest groups in Kenya and South Africa had little opportunity to contribute to the negotiating positions taken by their countries at international level? Since public engagement is endorsed in both the UNESCO declarations and the GGI proposals, the chapter will also trace the degree to which consultation takes place in Kenya and South Africa between government departments, experts and the general public on domestic

policy on genetics and bioethics. It will end by considering the implications of these various findings for the proposed membership of the GGI.

Chapter 6 will examine the content and implementation of the UNESCO declarations. To begin, it will ask how far the declarations are characterised by the ambiguity and compromise common to many regimes. Did their non-binding nature render them relatively quick to negotiate and amenable to future adaptation? Are they weaker than binding instruments, as per conventional regime interpretations, or do they enable states to strive for higher standards, as Victor *et al* might predict? Concerning implementation, the chapter will first analyse UNESCO's efforts to realise the declarations' norms. On the management side, how effective is the Bioethics Programme in encouraging states to take up the declarations? Are its capacity building activities hampered by constrained finances, in line with Young's observations? On the enforcement side, the reporting mechanisms attached to the declarations, where active, will be appraised as a system of implementation review (SIR), in terms of the responses they have incurred from member states. Turning then to the national level, the chapter will probe whether the declarations have made an impact on states' laws, regulations or policies, to the extent that this can be measured. It will explore in depth how far the declarations' norms have been adopted, directly or indirectly, into the bioethics systems of Kenya and South Africa, in what ways they have been tailored to local contexts and in which areas their implementation may depend on further support. It will also consider whether the GGI, if established, would duplicate or supplement the declarations' norms and associated activities.

Where the empirical data highlight that the governance of genetics and bioethics might be improved, Chapter 7 will discuss whether this could be achieved by changing elements of the regime that is the UNESCO declarations or whether a new form of governance, such as the proposed GGI, is also needed. In terms of power differentials, might measures similar to those recommended by Chasek and Rajamani for increasing the participation of developing countries in international negotiations be applied to UNESCO? If so, this could



have positive implications for the GGI, should it rely on UNESCO to facilitate the involvement of poorer states, as proposed by Rischard on the grounds that IGOs can ensure fair representation. On the question of representation and accountability, would any of the suggestions put forward by Samhat and Ellis, Rischard, Slaughter or Held and Archibugi be practicable in genetics and bioethics governance, for either UNESCO or the GGI? If greater input from experts could enhance the quality and legitimacy of decision-making, for example, from which sectors and by what criteria should they be selected? If all those interested in or potentially affected by genetic and biomedical research must be given the opportunity to participate, should this be through government representatives, civil society organisations, internet polling or multilayered public fora?

Not only an organisation's membership but also the nature and number of its rules and procedures will affect the type and content of any norms it elaborates. The approaches to governance of the writers named above each include means by which interest-based bargaining could be avoided. Rischard and Held promote an ethos of impartiality, whilst Slaughter, Samhat and Ellis emphasise the value of discussion and deliberation. Would such measures and activities help the GGI simultaneously maintain its rubrics of informality and southern leadership? Where agreement except on the lowest common denominator proves impossible, Slaughter endorses the principle of 'legitimate difference'. The need for a universal approach to genetics and bioethics, albeit applied as appropriate in different cultural settings, is the *raison d'être* of the three UNESCO declarations and a key justification for the GGI proposals. Thus whether this is the right approach will be crucial to the efficacy of either mechanism as a governance tool.

The question of what would be the most effective means of securing the implementation of the UNESCO declarations revolves around the issue of state sovereignty. If this is to remain sacrosanct, how might any states which have not yet adopted the declarations be persuaded or encouraged to do so? In the context of issue-based global networks, Rischard endorses the use of reputational effects to shame renegade actors into

complying with issue-specific norms. Whether the UNESCO declarations yet garner sufficient leverage that such tactics could be employed will thus be explored. Spun more positively, it might be that a Slaughter-like network (such as the GGI if it is indeed to be underpinned by governments) could foster inter-state peer pressure, the declarations' norms becoming gradually socialised through ongoing discussions among officials. At another level of abstraction, what would happen if states were to relinquish a part or the whole of their sovereignty? This would see UNESCO as the hub of a vertical network in a disaggregated world order or as an institution empowered to enforce human rights under cosmopolitan democracy. Chapter 7 will consider what evidence the powers, interests and values of the member states of UNESCO provide as to whether either scenario could be credited as in any way likely.

At a more practical level, it could be that the governance of genetic and biomedical research would be more effective if the international system was less *ad hoc* in nature. UNESCO and the proposed GGI are just two initiatives among several in the genetics and bioethics field. As government networks and cosmopolitan democracy would, according to Slaughter and Held, form a lattice or array of fora, could these provide viable systems for coordinated governance? How feasible are Rischard's and Slaughter's similar suggestions for the facilitative role that IGOs might play in GINs and horizontal government networks respectively, in the context of the relationship between UNESCO and the GGI? More broadly, it is pertinent to ask whether genetics and bioethics are best dealt with as single issues or as part of a more holistic approach to governance. Samhat and Ellis' civil society infused regimes, Slaughter's disaggregated networks and Rischard's GINs would each focus on a particular problem. Such mechanisms could prove poorly equipped to deal with genetics and bioethics, which are interwoven with other global issues such as inequalities of health and human rights. Cosmopolitan democracy, with its wide-ranging vision, might present a better alternative, able to address these issues in an integrated manner.



### **3.7 MOVING FORWARD**

This chapter has focused on theories of international relations. It has introduced particular explanatory and normative approaches to global governance and drawn out some of their possible strengths and weaknesses, forming a theoretical framework for the remainder of the thesis. The next chapter, as the complement to this one, outlines the methodology by which the research question was investigated empirically.

Stephen Hopgood, an international relations scholar, laments the lack of empiricism within his chosen field. That the discipline is mainly concerned with theory has, Hopgood claims, “deterred scholars from doing the primary empirical work about the institutions of world politics that would enable us to understand more of what is *actually going on* at the international level.”<sup>1</sup> The institutions he has in mind include both state and non-state actors—government elites, international organisations and NGOs—as well as less defined phenomena such as shared norms and beliefs. He concludes that paying more attention to the practice of international politics would carry certain methodological implications:

It may involve more openness to anthropological methods such as participant observation, archive work, interviews and questionnaires. This raises further questions about access, ethics, the volume of material, multi-sitedness (in transnational organisations), cultural and linguistic challenges.<sup>2</sup>

These few sentences encompass the processes by which this thesis has been researched. Methods included observation (albeit direct rather than participative), documentary analysis and semi-structured interviewing. In employing these, issues of access, ethics, transnational fields and cultural differences all had to be overcome. How this was achieved forms the substance of this chapter.

## **4.1 CASE STUDIES**

The UNESCO declarations on genetics and bioethics and the proposed Global Genomics Initiative form two cases for the study of global governance, with a focus on their impact in Kenya and South Africa. This section outlines how and why they were selected.

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<sup>1</sup> Hopgood, “Socialising IR,” 1.

<sup>2</sup> Ibid, 2 and 7.



### 4.1.1 What is a case study?

John Langrish defines a case study as “a research method, a way of finding out more about some aspect of reality through a very detailed analysis.”<sup>3</sup> Similarly, Robert Stake emphasises that case studies generate particular knowledge, but that they can also help increase understanding of a certain problem, issue or concept.<sup>4</sup> The “aspect of reality” of Langrish’s definition comprises the research focus; a case study is a device to enable discussion of this focus, with results expressed in function of it. Thus case studies are examples of recognised phenomena, in this case mechanisms for global governance.<sup>5</sup>

Robert Yin, in his seminal work on the case study method, describes three instances in which case studies might be a preferred means of research: “How?” or “Why?” questions are being investigated; the researcher has little control over events; and the focus is contemporary and ‘real-life’.<sup>6</sup> These conditions are mirrored by Alan Thomas: “In choosing a case study the researcher cannot control the conditions precisely but can still try to find a case which will provide evidence for or against a particular theoretical idea.”<sup>7</sup> For this research project, therefore, it was appropriate to choose a case study approach, because “How?” and “Why?” questions were being asked (in terms of why the UNESCO declarations and the proposed GGI might or might not be adequate mechanisms for the governance of genetics and bioethics and how this situation might, if necessary, be improved), the formulation of the UNESCO declarations or the GGI could not be controlled and the focus was contemporary, both theoretically and in ‘real-life’.

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<sup>3</sup> Langrish, “Case Studies as a Biological Research Process,” 357.

<sup>4</sup> Yanacopulos, “Researching Transnational Advocacy Networks,” 44, citing Stake, *The Art of Case Study Research*.

<sup>5</sup> Langrish, *op cit*, 360 and 362.

<sup>6</sup> Yin, *Case Study Research*, 1.

<sup>7</sup> Thomas, “Challenging Cases,” 308.

#### 4.1.2 Case study selection

As stated above, case studies are examples. In order to select appropriate cases for research, the question “Examples of what?” has to be addressed. A first stage in the process of answering this question is to review the relevant literature.<sup>8</sup> Citing Yin (1994 edition), Thomas asserts that case studies must be theory-led: “Ideas have to be worked out *before* you can decide which cases to study.” Evidence, once analysed, will then validate these ideas or challenge them, perhaps initiating a reconceptualisation of theory.<sup>9</sup>

The units of analysis in a case study may be clearly designated, such as individual persons or members-only groups, or more esoteric, in the form of events, processes or networks, for example. In either scenario, their definition is tentative and hence may be revisited during data collection as new discoveries are made, as was the case in this research project.<sup>10</sup> The units of analysis—governance mechanisms in genetics and bioethics and, within these, particular states—were defined and analysed with reference to a tentative theoretical framework and in function of the overarching research question. When new information came to light concerning the GGI and Slaughter’s work on networks, the framework changed and thus so did the conceptualisation of the cases, as outlined below. Kathleen Eisenhardt’s definition of theoretical sampling would seem to be a natural fit for this approach to case selection: “The cases may be chosen to replicate previous cases or extend emergent theory, or they may be chosen to *fill theoretical categories* and provide examples of polar types”<sup>11</sup> (*italics added*). More usually, however, ‘theoretical sampling’ is a term used in particular reference to grounded theory (see 4.3.1.1) and thus is not generally applicable to theory-led research.<sup>12</sup>

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<sup>8</sup> Langrish, op cit, 360, 362-363.

<sup>9</sup> Thomas, op cit, 313, 324 and 327.

<sup>10</sup> Yin, op cit, 23-24 and 55.

<sup>11</sup> Eisenhardt, “Building Theories from Case Study Research,” 537. Note, however, that Yin strenuously asserts that case studies are in no way samples. (Yin, op cit, 32.)

<sup>12</sup> Harding, “Grounded Theory,” 132; Hammersley, “Theoretical Sampling,” 298-299.



Yin states that every case should have a specific purpose within an investigation.<sup>13</sup>

Similarly, Stake holds that if more than one case is used, each must be instrumental in addressing the particular issue or problem identified in the research questions, thus forming a “collective case study.”<sup>14</sup> Langrish’s ‘taxonomic’ case study selection, under which cases are “examples of different parts of a taxonomy, i.e. the subgroups of the class being investigated,” is perhaps most closely aligned with the selection process employed in this project, particularly as the taxonomy can develop after research has started.<sup>15</sup> Yin’s “embedded case studies” are also relevant, which comprise more than one unit of analysis, or sub-units.<sup>16</sup>

Within this project, each case was chosen with a view to demonstrating particular aspects of the research focus (or “the class being investigated”), global governance. The higher order units of analysis were governance mechanisms for genetics and bioethics, the UNESCO declarations and the proposed GGI, while Kenya and South Africa were sub-units. The initial research plan was to examine the 1997 and 2003 declarations only, the *Universal Declaration on the Human Genome and Human Rights* and the *International Declaration on Human Genetic Data*, thus concentrating on human genetics. When it was discovered at the beginning of doctoral study that a declaration on bioethics was under negotiation, however, the remit was broadened, to take advantage of the opportunity to study an international instrument as it evolved. Furthermore, in the initial proposal the UNESCO declarations were the whole *raison d’être* of the research, with case studies to be done at country level. It was only when it was decided to investigate the GGI as well (which came to light through background research) that this changed. The focus expanded into global governance systems, the declarations and the GGI became the cases and the country studies turned into sub-units. At country level, also, the taxonomy developed as the project progressed; a final decision was made on South Africa as a fieldwork destination only after data collection in Kenya had been completed.

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<sup>13</sup> Yin, op cit, 47.

<sup>14</sup> Schwandt, *Qualitative Inquiry*, 26, citing and quoting Stake, op cit, 3-6.

<sup>15</sup> Langrish, op cit, 362.

<sup>16</sup> Yin, op cit, 42.

#### **4.1.3 Rationale for the UNESCO declarations and the GGI**

The UNESCO declarations and the proposed GGI were chosen as case studies because of their potential to illustrate and inform different approaches to global governance, both descriptive and normative. UNESCO and TJC, in its plans for the GGI, have similar aims in terms of knowledge sharing, capacity building and the promotion of universal ethical norms for genetic research, as shown in 2.3. The systems of governance by which each hopes to achieve these aims differ in important aspects, however, such as their place or otherwise within the UN system. UNESCO is an intergovernmental organisation and hence is of direct relevance to regime theory; the proposed GGI is explicitly modelled on contemporary international relations theory around networked governance. The two mechanisms may also have implications for cosmopolitan democracy, as they touch on human rights, inequalities of health (and how these might be addressed through a broad security agenda based on rational self-interest) and multilayered governance. The GGI, especially, helped to shape an evolving review of global governance, as it brought to light the particular approaches to networks espoused by Rischard and Slaughter. Thus case and theory selection were iterative processes, as described above.

#### **4.1.4 Rationale for Kenya and South Africa**

Given that the international relations discipline was providing the theoretical framework, it was decided that fieldwork should be undertaken in more than one country. Rather than facilitating a strict comparison between states, this has enabled relationships between international and national levels of governance to be examined in different contexts. 3.3.1 highlighted that regime theorists have consistently called for more studies on the impact of regimes at national level. With regard to the UNESCO declarations, whether and how they are actually applied by states has so far been under-researched. Of the several publications on the declarations (many of which are cited in this thesis), the few that



consider implementation focus on UNESCO's capacity building programmes rather than the efforts of individual countries. The Kenyan and South African case study sub-units help to address this analytical oversight.

Within the boundaries of theory-led decision-making, pragmatism came into play in the selection of Kenya and South Africa as fieldwork destinations. (Several writers on case study methodology, including Yin, Langrish and Thomas, highlight that certain cases may be opted for, at least in part, for practical or pragmatic reasons.<sup>17</sup>) Reflecting personal interests, knowledge and linguistic limitations, Africa proved the continent of choice. A matrix of potential countries<sup>18</sup> and contacts was drawn up, using information gleaned from the internet, the human genetics literature and the department of Development Policy and Practice at the Open University. From these Kenya and South Africa were singled out, because they each engage in a significant amount of human genetic research and provide a base for relevant regional and international organisations. Furthermore, contact with key actors within them had previously been established.

A notable contact in Kenya was the National Commission for UNESCO, established through a conversation at a meeting in Paris in January 2005. Not only would the Commission prove invaluable in facilitating important interviews, it was also able to offer practical assistance in terms of transportation and communications in the field. Kenya provided a broad cross-section of potential participants, comprising policy-makers, academics and civil society representatives operating at local, national, regional and international levels. It has a plethora of institutions dealing with genetics and bioethics policy, ranging from UNESCO and the World Health Organization, to government departments such as the National Council for Science and Technology and the Ministry of Health, to university ethics committees and community advisory boards. As outlined in 2.4, substantial levels of genetic research are being conducted in Kenya, with scientists working within international collaborations to investigate the genetic basis for variable

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<sup>17</sup> Ibid, 78; Langrish, op cit, 362; Thomas, op cit, 321.

<sup>18</sup> The other countries were Egypt, Malawi, Nigeria and The Gambia.

human susceptibility to diseases like malaria, tuberculosis and HIV/AIDS. Also, regional organisations such as the African Biotechnology Stakeholders Forum, African Technology Policy Studies and the Africa Centre for Technology Studies have headquarters there. These last two organisations try to enhance capacity for policy-making in science and technology.

A practical reason for choosing South Africa as a fieldwork destination was that there are strong links between the Open University and the Africa Genome Education Institute, which became the host institution. The very fact that such an organisation exists in South Africa is indicative of the level of genetics activity being carried out there. The country also boasts an active bioethics scene (again, see 2.4). South Africa, then, like Kenya, could offer a diverse array of potential participants. A further reason for its selection was that it differs from Kenya in certain dimensions. Firstly, whilst Kenya has held a seat on the Intergovernmental Bioethics Committee of UNESCO since 1999, the year the committee first met, South Africa was a member only in the inaugural year (1998-1999). Thus South Africa's experience of the negotiation process for the 2003 and 2005 declarations and its relationship with the UNESCO Bioethics Programme will have been different from those of Kenya. Secondly, despite comprehensive effort, it was not possible to locate any corporate activity in human genetics in Kenya. Given that the GGI, if established, would be led from the South and include experts from the private sector among its membership, this was a disappointing outcome (one that perhaps mirrored TJCB's own failed efforts to recruit private sector actors to its 2002 genomics policy course in Nairobi<sup>19</sup>). South Africa houses a number of businesses involved in genetics and, through the National Biotechnology Strategy, promotes innovation and commercialisation in this field. This added dimension to the cross-section of potential participants was a key factor in choosing South Africa.

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<sup>19</sup> Smith, A *et al*, "'Harnessing Genomics to Improve Health in Africa' – An Executive Course to Support Genomics Policy."



## 4.2 FIELDWORK AND METHODS

The previous section outlined why a case study methodology was employed and how Kenya and South Africa were chosen as sub-units. This section describes how data were collected in the field. Observations, documents and interviews—three forms of evidence common to many case studies—have been accrued from a broad range of sources.<sup>20</sup> Its breadth derives not only from the several methods of enquiry, but also from diversity within these, as advised by Thomas; documents of different types were obtained from a variety of organisations and interviewees represented a cross-section of society.<sup>21</sup> Using multiple sources of evidence can reveal a swathe of different historical, attitudinal and behavioural themes and help to establish validity and reliability when these converge towards the same findings.<sup>22</sup> When reviewing interview data alongside a strategy document, for example, a researcher can test “‘stated interests’ and the ‘agreed history’,” or opinion against purported fact.<sup>23</sup> This technique is termed ‘triangulation’ and is demonstrated in the data analysis of Chapters 5 and 6.

### 4.2.1 Observations

Observer status was granted by UNESCO at a week of meetings in January 2005 of the Intergovernmental and International Bioethics Committees (IGBC and IBC), held in Paris and devoted mainly to discussions of the draft *Universal Declaration on Bioethics and Human Rights* (UDBHR). This entailed only peripheral involvement in the proceedings and then only during unofficial moments such as coffee breaks.<sup>24</sup> Direct observation as a

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<sup>20</sup> Eisenhardt, op cit, 534 and 537; Yin, op cit, 8.

<sup>21</sup> Thomas, op cit, 330.

<sup>22</sup> Yin, op cit, 98.

<sup>23</sup> Yanacopulos, op cit, 48. Where participants give different accounts of the same event or phenomenon, comparison with official records may help piece the story together. It must not be assumed, however, that executive documents are unbiased or value free. They were written for a purpose and audience different to that of a case study and its investigators and do not represent unmitigated truth. (Yin, op cit, 87 and 159.)

<sup>24</sup> This is in line with what Thomas Schwandt describes as the “traditional concept” of observation as a research method, whereby the “participant as observer... is peripherally involved or only marginally participates in the scene he or she studies.” (Schwandt, op cit, 107.)

research method is characterised by attention to detail.<sup>25</sup> In an attempt to capture as much information as possible, who said what was meticulously noted, as were overall impressions of the negotiation process. Unfortunately, the meetings of intergovernmental experts in April and June 2005 charged with finalising the declaration were closed sessions, so for data on these it was necessary to rely on official reports and firsthand accounts from interviewees.

The opportunity to observe the January negotiations constituted preliminary fieldwork. Seeing how UNESCO worked 'in the flesh', within both the official sessions and the breaks between them, gave a rich sense of the germane issues and enabled comparisons of theories about IGOs with practice. As Thomas Schwandt writes, "Direct firsthand eye-witness accounts of everyday social action have always been regarded as essential to answering the classic fieldwork question 'what is going on here?'"<sup>26</sup> Observations were augmented through informal conversations with members of both the IGBC and the IBC, as well as those representing other UN bodies or NGOs or attending in a personal capacity. It was partly through a preliminary interview with a delegate during a coffee break that Kenya became a clear choice as a fieldwork destination. Thus observation as a research method proved fruitful beyond data collection *per se*.

#### 4.2.2 Documents

Yin lists several advantages to using documents in research. Firstly, they are stable and can be referred to repeatedly; secondly, they can be used to verify names and details of events; and finally, they can provide broad coverage in terms of time and place. "For case studies," writes Yin, "the most important use of documents is to corroborate and augment evidence from other sources."<sup>27</sup> In this project, UNESCO reports, rules of procedure and

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<sup>25</sup> Ibid, 106.

<sup>26</sup> Ibid.

<sup>27</sup> Yin, op cit, 86-87.



delegate registers have complemented observational and interview data concerning international negotiations. Documents from other sources, such as the *Guidelines for Ethical Conduct of Biomedical Research involving Human Subjects in Kenya* and the *South African Ethics in Health Research: Principles, Structures and Processes* (both 2004), as well as information from websites and academic publications, have also been used to substantiate interview material. Moreover, at a practical level, websites and publications proved indispensable in identifying potential participants and drawing up interview schedules (see 4.2.3).

Several different types of document were collected from a wide range of sources, before, during and after interviews. These included NGO newsletters, brochures from government departments and national laws, as well as those highlighted above. As far as was possible documents were gathered systematically, which Yin stresses is important if selective bias is to be avoided.<sup>28</sup> UNESCO reports and papers were collated through a comprehensive trawl of the Bioethics Programme website; relevant Acts of Parliament for Kenya and South Africa were similarly obtained.<sup>29</sup> For each potential participant or their organisation, thorough internet searches were carried out, often throwing up reports and publications in addition to the web-based information itself. Other documents were only brought to light during interviews, another example of the integration between the three research methods.

#### **4.2.3 Interviews**

Interviews were carried out in France, the United Kingdom, Kenya and South Africa, between August 2005 and May 2006.<sup>30</sup> All the European interviews were with people connected with UNESCO in some way, one being a senior member of the Bioethics

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<sup>28</sup> Ibid.

<sup>29</sup> From [www.unesco.org/bioethics](http://www.unesco.org/bioethics), [www.kenyalaw.org](http://www.kenyalaw.org) and [www.info.gov.za/documents](http://www.info.gov.za/documents) respectively.

<sup>30</sup> With the addition of one telephone interview with a South African participant in July 2006.

Programme and the others delegates to the April and June 2005 intergovernmental meetings. The bulk of fieldwork was conducted in Kenya in Autumn 2005 and South Africa in Spring 2006, each trip lasting six weeks.<sup>31</sup> In Kenya, all the interviews apart from six took place in Nairobi, the remainder at a research institute in Kilifi. In South Africa, potential participants were more diversely situated, entailing stays in Cape Town, Durban, Johannesburg and Pretoria and day trips to Stellenbosch and Pietermaritzburg.

#### **4.2.3.1 Ethical review**

The research project has been approved by the Open University Human Participants and Materials Ethics Committee,<sup>32</sup> the Ministry of Education, Science and Technology in Kenya<sup>33</sup> and the Ethics Committee of the Human Sciences Research Council of South Africa<sup>34</sup> and registered in compliance with the Data Protection Act 1998. The information requested by each body differed in detail, but in essentials was very similar. In short, it was necessary to show that participants would be fully informed about the nature and purpose of the research and, having given their consent freely, would be entitled to withdraw it at any time; that data would be anonymised (unless a participant chose otherwise) and stored securely; and that research findings would be fed back on completion of the project. Gaining ethical approval from Kenya and South Africa followed the guidance of the Wellcome Trust, the project funders, under its policy document *Research Involving People Living in Developing Countries: Position Statement and Guidance Notes for Applicants*.<sup>35</sup>

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<sup>31</sup> 28 September to 9 November 2005 and 21 March to 2 May 2006 respectively.

<sup>32</sup> Ethical approval references HPMEC/06/#188/1, HPMEC/06/#170/1 and HPMEC/06/#236/1.

<sup>33</sup> Research permit number MoEST 13/001/35C 502/2.

<sup>34</sup> HSRC Research Ethics Committee Protocol REC 3/08/03/06.

<sup>35</sup> The position statement can be viewed at [www.wellcome.ac.uk/doc\\_wtd015295.html#P152\\_17101](http://www.wellcome.ac.uk/doc_wtd015295.html#P152_17101) (accessed 12 January 2006).



#### **4.2.3.2 Participant selection and recruitment**

As the research project is concerned with how actors from different levels and sectors (local to global and state and non-state) contribute to the governance of genetics and bioethics, it was important to recruit participants from international organisations, governments, civil society organisations, academia and the commercial sector. Potential interviewees were identified through various means: internet searches, literature reviews and snowball sampling (that is, recommendations from other participants) or a combination of all three. Snowball sampling happened both prior to travel and in the field. With each request for an interview, potential participants were asked whether they could recommend any other suitable contacts. Saturation was soon reached in this process, the same names recurring in each sector, which was a useful confirmation that the relevant experts in each country had been identified. Snowballing was particularly important in Kenya, where much planning had to be done *in situ*, owing to the limited availability of information and relatively low response rate to emails prior to travel. Several afternoons were spent making seemingly endless telephone calls to set up interviews. Unfortunately, despite persistence tempered with politeness, some potential participants were simply unavailable, a common and perhaps inevitable difficulty faced by qualitative researchers, which has to be taken into account when drawing conclusions.<sup>36</sup>

In the context of research on networks, Helen Yanacopulos suggests that a researcher might begin by interviewing key people within important hubs or nodes.<sup>37</sup> The host institution in Kenya, the National Commission for UNESCO, arranged several very helpful meetings at the beginning of the fieldwork period, with some of its advisors and representatives and an official at the National Council for Science and Technology. Similarly, by attending a conference organised by the Africa Genome Education Initiative at the start of the South African fieldwork, it was possible to meet face to face several potential participants who had previously been corresponded with by email. Thus some

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<sup>36</sup> Thomas, *op cit*, 315.

<sup>37</sup> Yanacopulos, *op cit*, 46.

introductions had been made before the interviews proper, which helped put people at their ease.

#### **4.2.3.3 Interview process**

In total 70 semi-structured interviews were conducted: 3 in Paris, 3 in the United Kingdom, 30 in Kenya and 34 in South Africa (for a full list see Appendix II<sup>38</sup>). Twelve of these would more properly be termed informal conversations, but nevertheless yielded useful information. Audio recording followed by transcription was the preferred method of data collection; where this was not possible notes were taken. Interviews lasted anything between twenty minutes and two and a half hours, depending on the time a participant had available and the information required. Question schedules were written with reference to background information and therefore tailored to each individual participant, as recommended by Herbert and Irene Rubin.<sup>39</sup> Nevertheless, each reflected common themes, with several questions appearing in most or all of the schedules. The semi-structured nature of the interviews meant that, despite the generic questions, participants could be allowed to explore interesting tangents as they arose. Eisenhardt describes this kind of systematic flexibility as “controlled opportunism.”<sup>40</sup> Combinations of organisation-specific and open-ended questions were asked, an example of the former being, “What type of genetics does your company do?” and of the latter, “What is your opinion on community consent?”<sup>41</sup> Depending on the participant’s profile, the nuance or emphasis of a question was adjusted; where a geneticist would have been asked about ethical practice, for example, a member of an ethics committee was asked about the processes by which ethical approvals are granted.

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<sup>38</sup> The data from four interviews or informal conversations have not been used in the thesis and thus the details of these are not included in the appendix.

<sup>39</sup> Rubin and Rubin, *Qualitative Interviewing*, 363.

<sup>40</sup> Eisenhardt, *op cit*, 539.

<sup>41</sup> Langrish, *op cit*, 363.



The thematic areas for the interviews were drawn from the embryonic theoretical framework and were designed to elucidate people's perspectives on the following: the profile of the UNESCO declarations; the adequacy of representation at international negotiations; the translation of international level guidelines to the national level; the legitimacy of state and non-state based international organisations; overlapping institutional remits; networking between different organisations and sectors; the relevance of purportedly universal ethical guidelines to developing countries; inequalities of health; and genetics and development. The emphasis of the planned questions shifted slightly as it became clear that few participants were aware of the declarations or the proposed GGI (see Chapter 5). Questions thus centred on the utility of international bioethics guidelines in general, the processes by which they are drawn up and some of the ethical principles common to many of them, such as benefit sharing and community consent. The need for this adjustment is well illustrated by the following anecdote from an early Kenyan encounter. On hearing that the interview would be mainly about the UNESCO declarations, one member of a research institution engaged in human genetics joked, "It may be quite brief."<sup>42</sup>

#### **4.2.4 Considerations**

Yin writes that a case should have a specific beginning and end.<sup>43</sup> Whilst in this instance the limits of the cases have been broad in temporal terms (discussion of the first declaration began in 1993 and implementation of all three is ongoing) and were certainly not delineated from the beginning of the study (investigation of the proposed GGI developing as new publications emerged), timing has had a significant bearing on the research. The UDBHR (2005) was adopted only during the Kenyan fieldwork period but several months prior to that in South Africa, which affected how questions were worded in each country and perhaps also awareness of the declaration among participants.

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<sup>42</sup> Interview with K\_07.

<sup>43</sup> Yin, op cit, 26.

Similarly, the journal article on the GGI that introduced Slaughter's work became available only a few days prior to departure for South Africa, thus a deeper understanding of her arguments was only possible once the majority of data had been collected. It is also worth noting that, through asking certain questions, information was disseminated by default. Several participants vowed to find out more about the declarations and the GGI and to link up with the relevant persons or organisations. Even if only a few actually did this, the findings of any future research in a similar area will have been affected.

### **4.3 ANALYSIS AND THEORY BUILDING**

So far the chapter has described why a case study approach was chosen and how data on the selected cases were collected. The following section turns to data analysis and extrapolation.

#### **4.3.1 Case study analysis**

As highlighted in 4.1, since there are clear similarities between the aims of the UNESCO declarations and the proposed GGI, but fundamental differences in their structural philosophies, it made sense to study both rather than either in isolation. At sub-unit level, it was hoped that conducting fieldwork in more than one country would strengthen any findings pertaining to the relationship between national and international level governance. These decisions mirror Thomas' advice to consider examining "logical alternatives."<sup>44</sup> The analytical benefits of conducting a multiple-case study are likely to be substantial, according to Yin, as convergent conclusions will be more powerful than those arising from a single case, thus extending the external generalisability "immeasurably."<sup>45</sup>

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<sup>44</sup> Thomas, op cit, 319-320.

<sup>45</sup> Yin, op cit, 53.



Employing a contrastive approach can increase credibility, because it “guards you against the common danger of merely collecting evidence in favour of your pet idea under the pretence that you are subjecting your hypothesis to severe testing.”<sup>46</sup> Comparing different theoretical possibilities may lead to useful insights, even if none are found to entirely account for the data, as the final explanation may incorporate elements of each. Cases selected because they differ in theoretically significant ways can provide distinctive answers to “How?” and “Why?” questions.<sup>47</sup> In this instance, the cases are not only explanatory but also exploratory. The approaches to global governance outlined in Chapter 3—international regimes, issue-based and government networks and cosmopolitan democracy—represent rival explanations of why effective governance of genetics and bioethics may not yet have been attained and possible models for how this might be achieved in future.

#### ***4.3.1.1 Inductive and deductive reasoning***

In the contrastive approach outlined above, there is a continuous cycle between ideas and data. Data enable the testing of ideas or theories, but may also point in a different direction or to the need for further research.<sup>48</sup> As stated in 4.1.2, Yin and Thomas believe case studies should be theory-led. Yin states, “The case study inquiry... benefits from the prior development of theoretical propositions to guide data collection and analysis.”<sup>49</sup> An alternative approach is that of grounded theory, whereby existing theories are turned to only once data analysis has been completed, to determine which best matches the ‘grounded theory’ generated.<sup>50</sup> The method used in this project falls somewhere in between, forming a deductive-inductive-deductive cycle. As shown in 4.1.3, the theoretical framework was preliminarily developed prior to data collection and was revised in line with discoveries as they arose. A theoretical framework does not equate to theoretical

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<sup>46</sup> Mukherjee and Wuyts, “Thinking with Quantitative Data,” 240.

<sup>47</sup> Thomas, op cit, 319, 323, 324, 331 and 332.

<sup>48</sup> Mukherjee and Wuyts, op cit, 243.

<sup>49</sup> Yin, op cit, 14.

<sup>50</sup> Harding, op cit, 132.

propositions, however. The framework provided the parameters for data collection and preliminary coding (see below), but within these the process was inductive: the aim was to see what the data revealed, rather than to search for evidence in support of particular propositions. This is a modification of Yin's model, in order to allow fluidity and avoid bias. Only once coding was completed, which in turn shaped the refining of the theoretical framework, was the extent to which the data fitted any of the four approaches to global governance examined.

The method described above—the cycle between inductive and deductive reasoning—could perhaps be described as 'semi-structured'. Semi-structured interviews give some direction, but allow flexibility to explore tangents and thus prevent contextual depth or important issues or ideas that had not previously been considered being missed. This same approach was taken to the analysis as a whole: the theoretical framework gave some boundaries and context, to avoid unwieldiness, but did not equate to overly prescriptive predictions. In their work on case studies, Thomas and Eisenhardt recommend similar techniques. Thomas advocates developing theoretical ideas in advance in order to know what to expect, but also being open to these expectations proving wrong or needing to be changed.<sup>51</sup> Eisenhardt writes:

Preordained theoretical perspectives or propositions may bias and limit the findings. Thus, investigators should formulate a research problem and possibly specify some potentially important variables, with some reference to extant literature. However, they should avoid thinking about specific relationships between variables and theories as much as possible, especially at the outset of the process.<sup>52</sup>

#### **4.3.1.2 Coding**

Yin emphasises that no original evidence should be lost through carelessness or bias, but should receive proper attention and be examined exhaustively. Applying such prudence

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<sup>51</sup> Thomas, op cit, 325 and 329.

<sup>52</sup> Eisenhardt, op cit, 536.



guards against the temptation to report only data that support a particular theory.<sup>53</sup> With this in mind, all interviews were fully transcribed and systematically coded. Coding can be done either *a priori*, when codes are developed and data then sorted into them, or *a posteriori*, so that codes are derived from data and are thus context-sensitive.<sup>54</sup> For this project both methods were used, the latter first.

The software Nvivo7, produced by QSR International, was used to code the interview transcripts *a posteriori*. An order for analysis was drawn up, by sector and by country. Where some participants could be placed into two or more sectors (for example, a scientist who also acted as a government or IGO advisor), the sector which had the most bearing on why they had been selected was chosen. Codes can be descriptive, thematic, nominal or categorical. Where mostly descriptive codes are used theorising may prove problematic, thus Schwandt (drawing on Anselm Strauss) recommends coding for “conditions, interaction among actors, strategies and tactics, and consequences.”<sup>55</sup> Given that this research project is mainly concerned with relationships between actors and organisations from different levels and sectors, the codes developed reflect this advice. Some of those used most frequently include “Linkages between sectors”, “Overlap – between layers”, “Local considerations”, “Representation” and “Expertise”.

With the initial coding in mind, the theoretical framework was revisited and refined. *A priori* coding was used when it came to writing up the empirical data in function of the framework. The transcripts were gone through a second time, in the same order as previously, but with a new set of codes already developed. Many of these codes were similar to those used before, such as “Negotiations – relations between states”, “Delegate selection/expertise” and “Social responsibility”. This second set of codes was also used to analyse the observational data from the IGBC and IBC meetings of January 2005.

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<sup>53</sup> Yin, op cit, 51, 105 and 137.

<sup>54</sup> Schwandt, op cit, 16.

<sup>55</sup> Ibid, 17.

### 4.3.2 Theory building

As has been demonstrated throughout this chapter, case studies are inextricably linked to theory. Langrish's question "Examples of what?" is analogous to the one James Rosenau deems essential for any budding theoretician, "Of what is it an instance?":

Of all the habits one must develop to think theoretically, perhaps none is more central than the inclination to ask this question at every opportunity. It must be a constant refrain, a melody that haunts every lurch forward in the process of moving from observations to conclusions. For to see every event as an instance of a more encompassing class of phenomena is to sustain the search for patterns and to avoid treating any phenomenon as inherently unique. To think theoretically is to be at home with abstractions, to generalize, to discern the underlying order that links otherwise discrete incidents, and such a mode of thinking cannot be achieved and maintained unless every observed phenomenon is approached as merely one instance of a recurring sequence.<sup>56</sup>

The answer to "Examples of what?", according to Langrish, will determine what is looked for.<sup>57</sup> In this research project, relationships between levels and sectors that might shed light on the efficacy or otherwise of existing and potential systems for the governance of genetics and bioethics have been investigated, with a view to testing and building international relations theories around regimes, networks and cosmopolitan democracy. This involved searching for patterns and thus not treating any phenomenon as unique, so as to "discern the underlying order."<sup>58</sup> The outcomes of such a process can run two ways. Firstly, theory may suggest ways in which policy might be improved and secondly, the cases may highlight previously unrecognised theoretical gaps or errors.<sup>59</sup> These possibilities are explored in the remainder of the thesis.

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<sup>56</sup> Rosenau, "Thinking Theory Thoroughly," 28.

<sup>57</sup> Langrish, op cit, 362.

<sup>58</sup> Rosenau, op cit, 28.

<sup>59</sup> Thomas, op cit, 331.



#### 4.4 FROM METHODS TO RESULTS

Langrish asserts that bringing together all the analytical threads from multiple case studies takes “skill, imagination, lateral thinking and perseverance.”<sup>60</sup> Their subsequent interpretation involves a certain amount of subjective judgement.<sup>61</sup> In the chapters that follow the data collected from observations, documents and interviews are presented and analysed, in function of the theoretical framework. It is hoped that the conclusions drawn, though subjective, will be judged valid.

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<sup>60</sup> Langrish, op cit, 364.

<sup>61</sup> Thomas, op cit, 331.

## **CHAPTER 5 REPRESENTATION, LEGITIMACY AND ACCOUNTABILITY**

This chapter explores issues of representation, legitimacy and accountability in the governance of genetic and biomedical research. It examines relationships between various actors during the drafting of the three UNESCO declarations and what this might mean for the proposed Global Genomics Initiative. The first section looks at the relative influence of developed and developing countries and state and non-state actors on the negotiation process at international level and how this might have affected the content of the declarations. Whether the structure of the proposed GGI might offer an improved balance between these sets of actors is also considered. The second section then probes how delegates from Kenya and South Africa were selected to attend the UNESCO negotiations and to what extent they truly represented their constituents. It will be shown that whether the declarations are perceived as legitimate tools for the governance of genetics and bioethics depends as much on whether people believe they were elaborated in an open, accountable and expert manner as on their status as non-binding instruments of international law. The Toronto Joint Centre for Bioethics has high hopes for the legitimacy of the proposed GGI, as follows: "The GGI could establish legitimacy on a global level. The key to this is strong leadership and inclusive membership."<sup>1</sup> The chapter ends with an assessment of whether the network could indeed garner legitimacy on these grounds.

### **5.1 INTERNATIONAL LEVEL**

UNESCO is a traditional intergovernmental organisation in that it is comprised of member states. It is these states that make final decisions on the organisation's activities, including the elaboration and adoption of international declarations. In this sense, then, the UNESCO declarations on genetics and bioethics form a state-centric regime. Non-state

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<sup>1</sup> Dowdeswell *et al*, "Realising the Promise of Genomics," 140.



actors were involved in their drafting, however, notably UNESCO's International Bioethics Committee (IBC). The following sections explore relations between member states of UNESCO within the organisation's Bioethics Programme, particularly developed and developing countries, as well as the roles played by other actors, such as the IBC, UNESCO's sister UN agencies and NGOs. Whether the proposed GGI might present a more equitable model is also examined.

### **5.1.1 Relations between states**

This section examines how far the observations of 3.5.2 with regard to the relative influence of rich and poor states on negotiation proceedings are borne out by UNESCO. Noëlle Lenoir, first President of the IBC, said in 1996 that “to involve the developing countries in the debate [on bioethics] is itself an ethical imperative.”<sup>2</sup> To this end, substantial efforts have been made to ensure the inclusion of these countries in decision-making, in terms of committee membership and the declaration drafting process. Developing countries appear to have made significant contributions to all three declarations, the UDBHR (2005) most especially.

#### **5.1.1.1 The Intergovernmental Bioethics Committee (IGBC)**

The UNESCO Bioethics Programme houses two committees, the Intergovernmental Bioethics Committee and the International Bioethics Committee, each of which has 36 members. The IGBC's mandate, as agreed by the Executive Board in 1998, is to “examine the advice and recommendations of the IBC, including those concerned with the follow-up of the Universal Declaration [UDHGHR, 1997].” The Committee is to inform the IBC and the Director-General of its opinions, which the Director-General may then submit

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<sup>2</sup> Lenoir, “Bioethics and UNESCO,” 12-22.

to member states, the Executive Board and the General Conference. It may also suggest proposals for following up advice and recommendations from the IBC.<sup>3</sup> More informally, at the Committee's second session in 2001, then chairperson Najib Ouariti suggested that "the IGBC must act as an essential relay between the IBC and all the Member States on the one hand and between the IBC and civil societies on the other."<sup>4</sup> (Whether it is doing the latter is open to question, as this chapter will show.) The IGBC converges every two years, with meetings open to the public unless it decides otherwise.<sup>5</sup> States hold seats for four years, half the membership being elected at each biennial General Conference (for example, eighteen members are serving terms from 2005-2009 and eighteen from 2007-2011).

The curtailed number of seats means that less than a fifth of states are directly represented on the IGBC. Kenya was a member during the elaboration of the 2003 and 2005 declarations but South Africa was not, for example. South Africa's first real input into the negotiation process for the UDBHR was at an intergovernmental meeting of experts in June 2005 (see next sub-section), by which time, in line with Chasek and Rajamani's observations, it seemed to one of its delegates too late to bring anything new to the table, "when we hadn't had a voice *a priori*."<sup>6</sup> Note, however, that other countries without an IGBC seat attended the Committee's meetings in January 2005 and made contributions as observers.<sup>7</sup> Moreover, the IGBC's reduced representation is mitigated somewhat by the seats being allocated according to regional groupings, in accordance with 155 EX/Decision 9.2 of the Executive Board. Thus the composition of the Committee is as follows:

- Western European states and others, including the US (Group I), 7 seats;
- Eastern European states (Group II), 4 seats;

<sup>3</sup> UNESCO, "Statutes of the International Bioethics Committee (IBC)," adopted 7 May 1998, 3.

<sup>4</sup> UNESCO, "Report of the Second Session of the IGBC," 1.

<sup>5</sup> UNESCO, "Intergovernmental Bioethics Committee: Rules of Procedure," adopted 14 May 2001, 2; UNESCO, "Committees and Organs Elected by the General Conference (33C)," ERC-2006/WS/2 (Paris: UNESCO, 2006), 53.

<sup>6</sup> Interview with SA\_23. The letters in the codes indicate where the interviews took place. Thus "SA" indicates South Africa, "F" France, "K" Kenya and "UK" the United Kingdom. For more details of interviews, including place and time and participant affiliation or background, see Appendix II.

<sup>7</sup> Member states were also consulted from the outset through a written consultation (see 5.1.1.2).



- Latin American and Caribbean states (Group III), 6 seats;
- Asian and Pacific states (Group IV), 7 seats;
- African and Arab states (Group V), 12 seats.<sup>8</sup>

The officers of the IGBC's Bureau represent a similar geographical dispersion, the chairperson coming from Italy, the vice-chairpersons from Saudi Arabia, Latvia, Uruguay and China and the rapporteur from Kenya.<sup>9</sup> Within the regional groupings, bigger states such as France, Russia, China and the United States of America tend to expect a permanent seat on the Committee, whilst smaller states rotate their memberships. This was described as "political wheeling and dealing" by a member of the Bioethics Programme's secretariat.<sup>10</sup>

#### **5.1.1.2 Declaration drafting and negotiations<sup>11</sup>**

##### ***UDHGHR (1997)***

As expressed by Lenoir, UNESCO has a long-standing commitment to involve developing countries in ethical debates. At its second meeting, the Legal Commission of the IBC appointed to draw up the declaration on the human genome discussed how it would proceed with its assigned task. It concluded, "One of the major objectives of the IBC is to set back the debate on ethics into a planetary context, by giving the opportunity to representatives of countries from the South to voice their concerns, often neglected in

<sup>8</sup> UNESCO, "Decisions Adopted by the Executive Board at its 155th Session," 155 EX/Decisions (Paris: 3 December 1998), 67; UNESCO, "What is an Electoral Group?" [http://portal.unesco.org/en/ev.php-URL\\_ID=31523&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=31523&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 16 August 2007). In 2004 UNESCO had 190 member states, divided between the five electoral groups as follows: Group I, 27; Group II, 24; Group III, 33; Group IV, 42; and Group V, 64. UNESCO, *Basic Texts* (Paris: 2004), 67-69.

<sup>9</sup> UNESCO, "Committees and Organs Elected by the General Conference (33C)," ERC-2006/WS/2 (Paris: 2006), 53. The Bureau is "responsible for coordinating the work of the Intergovernmental Committee, setting the date, time and agenda of meetings and in general for assisting the Chairperson in carrying out his/her duties." (UNESCO, "IGBC: Rules of Procedure," 2.) The officers listed were elected at the IGBC's January 2005 meeting, according to the electoral groups. (IGBC meeting, Paris, 24 January 2005, personal observation.)

<sup>10</sup> Interview with F\_01.

<sup>11</sup> The bulk of the data in this section necessarily relate to the UDBHR (2005), for three reasons: firstly, it was possible to observe some of the relevant meetings; secondly, more documentation is available concerning the roles played by individual states in the drafting; and thirdly, some of those involved in the negotiations were interviewed during fieldwork.

such discussions.”<sup>12</sup> How the Commission ensured that this objective was fulfilled in the elaboration of the UDHGHR cannot be corroborated, however, as UNESCO's book on the declaration's history, *Birth of the Universal Declaration on the Human Genome and Human Rights*, does not specify the input of individual states, nor does it include an account of the intergovernmental meeting of experts held in July 1997, which finalised the draft.<sup>13</sup>

### *IDHGD (2003)*

Although the IGBC appears to have played no role in the drafting of the declaration on human genetic data, states were able to contribute to the elaboration process on various occasions.<sup>14</sup> The first opportunity came in January 2003, when an “international consultation” was launched. An outline of the draft declaration and a questionnaire were sent to states and other stakeholders (see also 5.1.2.2). At first, very few replies were received, so the deadline for submission was extended; 42 member states eventually responded, 10 from Group I (out of 27 members), 8 from Group II (24), 6 from Group III (33), 6 from Group IV (42) and 12 from Group V (64). Thus there were proportionally more replies from developed countries than developing ones. The draft declaration was refined in light of the returned questionnaires, in preparation for an Intergovernmental meeting of experts (IGE meeting) in June 2003, with greater emphasis placed on issues pertinent to developing countries, such as benefit sharing and international cooperation. (Whether it was states or non-state actors, or both, calling for this greater emphasis is not specified in the consultation report.)<sup>15</sup>

The IGE meeting was poorly attended. Only 57 member states sent delegates, of whom 34 took part in the meeting's general debate. The reason for this low attendance is not clear. It is possible that some states did not consider the draft declaration of particular

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<sup>12</sup> UNESCO, *Birth of the Universal Declaration on the Human Genome and Human Rights*, 37.

<sup>13</sup> Roberto Andorno, in a book chapter on the declaration, notes that there were 81 member states at the IGE meeting. (Andorno, “Seeking Common Ground on Genetic Issues,” 106.)

<sup>14</sup> In a timetable of the drafting process no mention is made of the IGBC. (UNESCO, “Newsletter: Social and Human Sciences,” October-December 2003, 19.)

<sup>15</sup> UNESCO, “Meeting of Government Experts Responsible for Finalizing the Draft International Declaration on Human Genetic Data: Summary of the International Consultation,” 1, 2 and 11.



relevance to their national needs or interests. Group I was more strongly represented than the other four, despite its being one of the smaller regional groupings.<sup>16</sup> Furthermore, consonant with the findings of the 2003 UNDP study on global public goods, the larger delegations were chiefly from Group I states. Whilst most states sent one or two representatives, the United States (at the time not even a member of UNESCO) sent six, Germany five, France six and Tunisia five.<sup>17</sup> The meeting supported the revised provisions on benefit sharing and international cooperation, particularly those concerning donor communities and scientific researchers in developing countries. Some delegates wanted to see these provisions strengthened further, but others objected, foreseeing clashes with the patent system and national standards for sample donation and research. As is often the case in regime negotiations, then, a compromise was reached: the original formulations were retained, with the addition of a clause stressing the need to build the capacity of developing countries to collect and process human genetic data.<sup>18</sup>

#### *UDBHR (2005)*

As for the IDHGD (2003), the first contributions by states to the drafting of the bioethics declaration were made through a written consultation. A questionnaire on what the declaration's aims, structure and content should be was sent to all member states, associate member states and permanent observer missions.<sup>19</sup> Of the sixty-seven questionnaires returned, 21 were from Group I, 10 from Group II, 6 from Group III, 8 from Group IV, 21 from Group V and one from a permanent observer. The greater number of responses to this questionnaire in comparison to that for the IDHGD is thus mainly attributable to states in Groups I and V (Western European states and others and African and Arab states). A second written consultation was launched in October 2004, to which only 31 member states and permanent observers responded (although other bodies also

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<sup>16</sup> There were 16 delegates from Group I, 9 from Group II, 10 from Group III, 7 from Group IV and 15 from Group V. (UNESCO, "Meeting of Government Experts Responsible for Finalizing the Draft International Declaration on Human Genetic Data: Final Report," 1.)

<sup>17</sup> UNESCO, "Meeting of Government Experts Responsible for Finalizing the Draft International Declaration on Human Genetic Data: List of Participants," SHS/EST/03/CONF.203/INF.2 (Paris: 30 June 2003), 1-9.

<sup>18</sup> UNESCO, "Meeting of Government Experts Responsible for Finalizing the Draft International Declaration on Human Genetic Data: Final Report," 6 and 7.

<sup>19</sup> UNESCO, "Report by the Director-General on the Drawing Up of a Declaration on Universal Norms on Bioethics," 1.

contributed; see 5.1.2.2).<sup>20</sup> This second consultation prompted the addition of an article specifically devoted to social responsibility (see below).

In terms of participation at meetings concerning the draft UDBHR, this was ostensibly fair and equal among member states. The chairpersons of the IGBC and IBC meetings in January 2005<sup>21</sup> went to great pains to ensure that members had equal opportunities to contribute, as enjoined by the IGBC rules of procedure: "The Chairperson shall call upon participants in the order in which they signify their wish to speak."<sup>22</sup> This practice was also stipulated for the IGE meetings held in April and June 2005 and an attendee confirmed these were conducted in said fashion: "From my own observations everybody had a right to say whatever he or she wanted to say. After all, they were representing their states."<sup>23</sup> Nevertheless, some participants played a greater part in these sessions than others. At the January 2005 IGBC and IBC meetings, representatives from Germany, the United States, the Russian Federation, Brazil and Egypt each made fifteen or more comments, whereas those of Malawi, Mozambique and Togo made none at all.<sup>24</sup> Furthermore, some attendees at the IGE negotiations commented in interviews that the coffee breaks were when things were really decided, which also seemed to be the case at the January meetings.<sup>25</sup>

A Kenyan participant at the IGE meetings felt that those countries that had a long history in bioethics had an advantage over those just starting in the field.<sup>26</sup> This perhaps mirrors

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<sup>20</sup> UNESCO, "Towards a Declaration on Universal Norms on Bioethics: Progress Report January 2005," PowerPoint presentation available at [http://portal.unesco.org/shs/en/file\\_download.php/50523d754289e00aad6d16990d576e22Bioethics+Declaration\(jan.2005\).ppt](http://portal.unesco.org/shs/en/file_download.php/50523d754289e00aad6d16990d576e22Bioethics+Declaration(jan.2005).ppt) (accessed 9 July 2007).

<sup>21</sup> The IGBC met to discuss the draft declaration on 24 and 25 January 2005. On 26 and 27 January it continued this discussion at a joint meeting with the IBC. On 28 January the IBC held a further meeting, attended by several IGBC representatives, to revise the draft in light of the week's discussions.

<sup>22</sup> IGBC and IBC meetings, Paris, 24 to 28 January 2005, personal observations; UNESCO, "IGBC: Rules of Procedure," 2.

<sup>23</sup> Interview with K\_01; UNESCO, "First Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics: Provisional Rules of Procedure," SHS/EST/05/CONF.203/2 (Prov.) (Paris: 4 February 2005), 3. The rules of procedure for the IDHGD (2003) IGE meeting were very similar; those for the UDHGHR (1997) meeting are not available. (UNESCO, "Meeting of Government Experts Responsible for Finalizing the Draft International Declaration on Human Genetic Data: Provisional Rules of Procedure," SHS/EST/03/CONF.203/2 (Prov.) (Paris: 28 May 2003), 3.)

<sup>24</sup> IGBC and IBC meetings, Paris, 24 to 28 January 2005, personal observations.

<sup>25</sup> Ibid; interviews with UK\_01 and UK\_02.

<sup>26</sup> Interview with K\_01.



the concerns of UNDP and Held about differences between countries in levels of expertise at international negotiations. In terms of numbers, also, an examination of the lists of delegates reveals that some countries were able to send bigger entourages than others to both the January IGBC and IBC sessions and the two IGE meetings. A conference on biodiversity was being held in the same week as the former, with at least one African delegate obliged to cover both at once; representatives of other African countries were not present for significant periods in the meetings.<sup>27</sup> Of the 75 and 90 states that attended the April and June IGE meetings, 59 and 68 respectively sent only one or two delegates. By contrast, Canada, France and the United States sent between five and nine.<sup>28</sup> The chief South African representative at the June meeting commented, "I was left as the sole representative from South Africa (unlike other countries who were much more organised and had a panel of experts representing them)." She went on to say, "The bigger boys came with a whole network of people that spoke and contributed to each thing... I felt uniquely alienated... without that intensive support."<sup>29</sup>

Some countries sent no representative at all. Of UNESCO's 190 member states at the time, exactly half attended the April or June meetings. As at the IGE meeting for the IDHGD (2003), there were proportionately more countries from Group I than from the other four groups.<sup>30</sup> It is possible to speculate about why this should have been the case. Firstly, some developing countries may have considered bioethics to be a First World issue and therefore of little importance to them. One African delegate at the January 2005 IGBC and IBC meetings commented anecdotally that bioethics was not of general

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<sup>27</sup> Interview with F\_02; IGBC and IBC meetings, Paris, 24 to 28 January 2005, personal observations. See also UNESCO, "Fourth Session, Intergovernmental Bioethics Committee (IGBC): Provisional List of Participants," SHS/EST/CIGB-4/INF.2 (Paris: 25 January 2005).

<sup>28</sup> UNESCO, "First Intergovernmental Meeting of Experts Aimed at Finalizing a Draft of a Declaration on Universal Norms on Bioethics: List of Participants," SHS/EST/05/CONF.203./INF.1 (Paris: 6 April 2005), 1-14 and UNESCO, "Second Session of the Intergovernmental Meeting of Experts Aimed at Finalizing a Draft of a Declaration on Universal Norms on Bioethics: List of Participants," SHS/EST/05/CONF.204./INF.1 (Paris: 25 June 2005), 1-16. Canada, France and the United States sent six, seven and eight delegates respectively to the April meeting and five, eight and nine to the June meeting.

<sup>29</sup> Interview with SA\_23.

<sup>30</sup> At the April IGE meeting there were 20 states from Group I, 8 from Group II, 17 from Group III, 9 from Group IV and 21 from Group V; at the June meeting there were 22 from Group I, 13 from Group II, 20 from Group III, 12 from Group IV and 23 from Group V. (UNESCO, "First Intergovernmental Meeting of Experts: List of Participants," 1-14 and "Second Intergovernmental Meeting of Experts: List of Participants," 1-16.)

concern in his country, as people had more immediate problems to deal with.<sup>31</sup> Secondly, representatives from developed countries would likely have had the double bonus of greater funding for travel combined with a shorter distance to cover, compared to their developing country counterparts. A member of the Kenya National Commission for UNESCO, who had attended several meetings in Paris, noted that “the participation from the developing countries is quite low.” This can be problematic, he said, because if countries do not participate in negotiations their interests cannot be addressed.<sup>32</sup> His colleague, the Kenyan UNESCO Chair in Bioethics, who attended the April and June IGE meetings, made a similar observation, citing lack of resources as the reason why several African countries could not send representatives. (For both the IGBC and IGE meetings, states had to cover their attendance costs.<sup>33</sup>) He thought it would be harder for these states to visualise how to implement the declaration, because they had not been involved in its elaboration.<sup>34</sup> As only cosmetic changes were made to the declaration's final draft at the General Conference at which it was adopted, it would seem that those states which did not attend the IGE meetings had little input into the UDBHR.

Although developing countries may have been disproportionately few in number at negotiations, the UDBHR represents a significant effort to address their needs and concerns. This had been the intention from the outset. The IBC, in its initial report on the possibility of a bioethics declaration, suggested that the priorities of such an instrument should be meeting vital needs and increasing access to drugs and the drafting group, at its first meeting, decided that the UDBHR should “above all respond to the concerns of developing countries.”<sup>35</sup> By forming common regional fronts on some issues, these countries were able to voice their concerns relatively loudly, in line with Chasek and Rajamani's observations on the power of coalitions. This represented a compromise on

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<sup>31</sup> IGBC and IBC meetings, Paris, 24 to 28 January 2005, informal conversation.

<sup>32</sup> Interview with K\_16.

<sup>33</sup> UNESCO, “First Intergovernmental Meeting of Experts Aimed at Finalizing a Draft of a Declaration on Universal Norms on Bioethics,” CL/3746 (undated letter of invitation from the Director-General, sent to National Commissions and permanent delegations), 1.

<sup>34</sup> Interview with K\_01.

<sup>35</sup> UNESCO, “Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics,” 4; UNESCO, “First meeting of the IBC Drafting Group for the Elaboration of a Declaration on Universal Norms on Bioethics,” 3.



states' individual views on certain points, in order to strengthen their negotiating positions overall. Describing the difficulties in balancing the national interest with broader concerns, the Kenya National Commission for UNESCO representative said, "It's a challenge, because you as a country may be having certain inclinations, but we are also bound by what they call the 'African Unity'."<sup>36</sup> Another African participant also noted that people from the same region would speak with a common voice. She remarked that on issues such as women and vulnerable communities, the Latin American countries, together with India, were the most vocal, "so it seemed as if the world dynamics are still based on the developed and the developing worlds and it's the fact of life."<sup>37</sup>

The issue for which the regional groupings were most visible was that of social responsibility and health. This was initially introduced by the Latin American states and later also backed by the Asian and African groups.<sup>38</sup> It was during the second written consultation and a series of regional meetings towards the end of 2004 (see 5.1.2.2) that the issue gained real prominence. Brazil and Paraguay argued strongly for a greater emphasis on a "social agenda." The former wrote, "The draft text... is too narrow in scope in relation to the development of aspects connected to economic, social and cultural rights, which represent the 'social agenda' of the draft declaration."<sup>39</sup> Paraguay's response was in a similar vein:

*The Declaration has left out or has yet to include themes closely tied to bioethics, such as access to health care and drugs and the right to a life of dignity and a healthy environment... A declaration cannot be universal if it leaves out these and other problems which affect perhaps the majority of the world's population, who are faced with poverty, hunger, illness, social exclusion and, in many cases, violence.*<sup>40</sup>

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<sup>36</sup> Interview with K\_16.

<sup>37</sup> Interview with SA\_23.

<sup>38</sup> Interview with F\_01.

<sup>39</sup> UNESCO, "Results of the Written Consultation on the Third Outline of the Text of a Declaration on Universal Norms on Bioethics (27 August 2004)," 2.

<sup>40</sup> Ibid, 7.

In the light of such comments, the IBC drafting group added an article on social responsibility to the draft text, the concept having previously featured in the preamble only.<sup>41</sup>

The formulation of the article came in for much discussion at the January 2005 IGBC and IBC meetings, where it was described by Justice Kirby, chairperson of the IBC drafting group, as softer than the 'right to health', but innovative.<sup>42</sup> Several Latin American delegates emphasised the importance of the article and argued that it should go further. Other participants thought that developmental goals were beyond the scope of the declaration. The dichotomous opinions did not represent a straightforward split between North and South, however; Chile expressed the view that issues such as poverty and illiteracy were not bioethical issues, whilst Finland supported the inclusion of access to nutrition and water, seeing these as important in preventing ill-health.<sup>43</sup> At the final IGE session in June 2005, developing countries are reported to have declared the article on social responsibility to be of "paramount importance." It was approved by consensus by the meeting, a somewhat unexpected outcome given the previous opposition of some member states.<sup>44</sup> Moreover, the final article is more strongly worded than its original formulation, pronouncing "the enjoyment of the highest attainable standard of health" a human right. This aspect of the declaration may help to dispel the belief, highlighted in Chapter 2, that 'universal' bioethics is in fact simply western bioethics.<sup>45</sup>

While the Latin American countries were successful in keeping social responsibility on the agenda during the drafting of the UDBHR, this was not the case for every issue. Members

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<sup>41</sup> UNESCO, "Sixth Meeting of the IBC Drafting Group for the Elaboration of a Declaration on Universal Norms on Bioethics," 3.

<sup>42</sup> IGBC meeting, Paris, 24 January 2005, personal observation.

<sup>43</sup> IGBC and IBC meetings, Paris, 24 to 28 January 2005, personal observations.

<sup>44</sup> UNESCO, "Second Session of the Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics: Final Report," 6; Interviews with F\_01 and F\_02. Germany and the United States, for example, opposed the inclusion of articles dealing with social and economic development, not because they considered these issues unimportant, but rather as beyond the scope of bioethics and being dealt with in other fora. (UNESCO, "Second Session of the Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics: Compilation of Proposed Amendments Submitted by Member States," 3, 4 and 38.)

<sup>45</sup> Interview with F\_01; comment by Justice Kirby, IGBC meeting, Paris, 24 January 2005 (personal observation).



of the Executive Board from Group III (Latin American and Caribbean states) had wanted the declaration to cover reproductive human cloning, sex selection, pharmacogenetics, germ-line interventions and beginning and end of life, but these were deemed too controversial to enable consensus.<sup>46</sup> Developing countries as a whole were very concerned with intellectual property rights, but agreement on this subject was also considered impossible.<sup>47</sup> (One participant at the IGE meetings commented that it was left out because it would “bring a lot of politics,” although the explanation given in the report of the June meeting was that it falls within the competence of other IGOs.<sup>48</sup>) Overall, however, the declaration is seen to cover several themes particularly pertinent to developing countries. Indeed, those from Kenya involved in the drafting process declared themselves mostly satisfied with the final outcome.<sup>49</sup> Thus the IBC’s foremost aim, as expressed by Lenoir, appears to have been met in the case of the UDBHR.

### **5.1.2 Non-state actors**

The previous section discussed the role of states in UNESCO’s Bioethics Programme as a whole and in the drafting of its three declarations on genetics and bioethics specifically. This section looks at non-state actors in a similar vein, firstly the IBC and secondly other stakeholders.

#### **5.1.2.1 International Bioethics Committee (IBC)**

The IBC was the prime actor in the elaboration of the text of all three declarations.

Although one of the Committee’s defining characteristics is that it is made up of

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<sup>46</sup> UNESCO, “Fifth meeting of the IBC Drafting Group for the Elaboration of a Declaration on Universal Norms on Bioethics,” 2; UNESCO, “Elaboration of the Declaration on Universal Norms on Bioethics: Second Outline of a Text,” SHS/EST/04/CIB-Gred-2/4 Rev. 1 (Paris: 27 July 2004), 4.

<sup>47</sup> Interview with UK\_01.

<sup>48</sup> Interview with K\_01; UNESCO, “Second Intergovernmental Meeting of Experts: Final Report,” 3.

<sup>49</sup> Interviews with K\_01 and K\_16.

independent experts, its authority is seen to derive from the fact that it sits within an intergovernmental body. Hence during the drawing up of the UDHGHR (1997) it was considered to be “the only international body working in the field of bioethics.”<sup>50</sup> The IBC has various functions, including the promotion of reflection and education around ethical issues, cooperation with IGOs, NGOs and bioethics committees and follow-up on the three declarations.<sup>51</sup> Its system of appointment is perhaps less political than that of the IGBC. Members are selected by the Director-General according to recommendations by member states, but as independent advisors:

The Director-General appoints the IBC's 36 members to serve in their personal capacities for four-year terms. The selection is made taking into account cultural diversity, balanced geographical representation and nominations from some States of qualified specialists in the life sciences and in the social and human sciences, including law, human rights, philosophy, education and communication.<sup>52</sup>

Achieving this cultural, geographical and disciplinary diversity can be a challenge when some parts of the world, such as Africa, are seen to have relatively few of the required specialists.<sup>53</sup> Whether a nominee is appointed will depend partly on whether they meet the necessary profile to secure a balanced membership. For the two-year period during which the UDBHR (2005) was elaborated, the Committee had several medical experts but would have welcomed more bioethicists. To facilitate selection in recent years, the Bioethics Programme has offered to help member states identify suitable candidates. A country offering a range of possible members, each with different areas of expertise, also works well.<sup>54</sup>

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<sup>50</sup> UNESCO, *Birth of the Universal Declaration on the Human Genome and Human Rights*, 1.

<sup>51</sup> UNESCO, “Statutes of the International Bioethics Committee (IBC),” 1; IDHGD, article 25; UDBHR, article 25.

<sup>52</sup> UNESCO, “International Bioethics Committee (IBC),” [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=1879&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html#3](http://portal.unesco.org/shs/en/ev.php-URL_ID=1879&URL_DO=DO_TOPIC&URL_SECTION=201.html#3) (accessed 17 August 2007).

<sup>53</sup> Interview with F\_01. In 2004-05, for example, the Committee had 35 members, split across the electoral groups as follows: Group I, 11; Group II, 3; Group III, 6; Group IV, 7; and Group V, 8. Thus there were fewer experts from African and Arab states and more from Western European and other states than would have been the case if the IBC had followed the ratios stipulated for the IGBC. (UNESCO, “Composition of the International Bioethics Committee of UNESCO (IBC) (2004-2005),” CIB/04-05/INF 1 (Rev. 3) (Paris: 20 December 2004.)) The smaller groups that are formed to write reports or draw up declarations also aim for a geographical mix, including a substantial membership from developing countries. The drafting group for the IDHGD (2003), for example, included IBC experts from Argentina, the Philippines, Nigeria and India. (UNESCO, “Public Hearings Day on Human Genetic Data,” 2.)

<sup>54</sup> Interview with F\_01. In the year 2004-05, the composition of the Committee was as follows: members of national bioethics committees, 12 (of which 8 were Chair or President); present or former members of other bioethics or ethics committees, 9; academics in bioethics or philosophy, 9; academics in medical or genetic



IBC meetings are held in public. The ninth session of the IBC, for example, held in Canada in 2002, attracted around 250 participants from 60 countries.<sup>55</sup> At the thirteenth session (held in Paris and attended by 200 participants from 40 countries), the chairperson of the IBC, Nouzha Guessous Idrissi, remarked that the meeting would continue the debate on social responsibility and health initiated at the previous session, “to give the Committee an opportunity to pursue its work openly and transparently.”<sup>56</sup> Although these numbers and intentions are impressive, it remains the case that the work of UNESCO in bioethics is not particularly well-known (see 5.2).

#### **5.1.2.2 Other non-state actors**

Non-state actors were given the opportunity to share their opinions on the drafts of all three UNESCO declarations, through written and verbal consultations and as observers at meetings. The written consultations, in the form of questionnaires, were extensive. For the UDHGHR (1997), in a “vast and informal” consultation, the draft declaration was sent to around 300 institutions and individuals, including other UN agencies, national bodies, NGOs, ethics committees, universities and prominent intellectuals, in line with then Director-General Federico Mayor’s wish that it should be used as “an instrument of intercultural dialogue.” Responses to the questionnaire were discussed in detail by the Legal Commission and the IBC and formed the basis of a new version of the declaration. At the Commission’s final meeting, members were urged to disseminate the revised draft as widely as possible.<sup>57</sup> The results of the questionnaire for the IDHGD (2003) similarly led to changes in the draft (see 5.1.1.2), on which organisations at international, regional and national levels and more than 100 bioethics experts had been invited to share their opinions. Replies were received from the Office of the United Nations High Commissioner

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sciences, 16 (plus 1 physician); academics in law, judges or those involved in human rights, 10 (some members are in 2 or 3 categories). (UNESCO, “Composition of the IBC (2004-2005).”)

<sup>55</sup> UNESCO, “Report by the Director-General on the Work of the IBC and the IGBC,” 1.

<sup>56</sup> UNESCO, “Thirteenth Session of the IBC,” 1.

<sup>57</sup> Lenoir, “Bioethics and UNESCO,” 12-22; UNESCO, *Birth of the Universal Declaration on the Human Genome and Human Rights*, 57-58, 61, 67 and 110.

for Human Rights, 12 NGOs (including CIOMS, HUGO and the Joint Programme Commission on Science and Ethics<sup>58</sup>), 22 ethics bodies, 6 data protection agencies and 21 “eminent personalities” or former IBC members.<sup>59</sup>

For the UDBHR (2005), UNESCO considered the involvement of actors other than member states to be crucial to the drafting of the declaration. Its website read, “Only the participation of all the actors concerned could ensure that all the different perceptions of ethical and legal issues are taken into account.”<sup>60</sup> In October 2004 the third outline of the text was sent for comment to IGOs, NGOs, relevant national bodies and around 40 independent experts. Responses were duly received from 4 IGOs, 14 NGOs, 14 national bioethics committees and 12 individuals. These replies, together with those of member states, were discussed at the sixth and final meeting of the IBC drafting group, which drew up the draft version of the declaration that was subsequently debated at the IGBC and IBC meetings in January 2005.<sup>61</sup>

The verbal consultations on the 2003 and 2005 declarations were also comprehensive.<sup>62</sup> For the IDHGD, a Public Hearings Day<sup>63</sup> was held in Monaco in February 2003, at which Pierre Sané, Assistant Director-General for the Social and Human Sciences sector, stressed “the importance that should be attached to the involvement of civil society in the bioethical debate and the transparency of the IBC’s work.”<sup>64</sup> The statements of speakers, representing international bodies such as the World Medical Association, developing

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<sup>58</sup> HUGO is the Human Genome Organisation, CIOMS the Council for International Organizations of Medical Sciences. The Joint Programme Commission on Science and Ethics comprises 32 member organisations.

<sup>59</sup> UNESCO, “Meeting of Government Experts Responsible for Finalizing the Draft International Declaration on Human Genetic Data: Summary of the International Consultation,” 1 and 12-15.

<sup>60</sup> UNESCO, “Towards a Declaration on Universal Norms on Bioethics,” [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=1883&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=1883&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 7 October 2004).

<sup>61</sup> UNESCO, “Towards a Declaration on Universal Norms on Bioethics,” PowerPoint presentation; UNESCO, “Report by the Director-General on the Drawing up of a Declaration on Universal Norms for Bioethics,” 1.

<sup>62</sup> The Co-ordinator of the Bioethics Commission of the International Federation of Philosophical Societies and the President of the International Court of Justice gave presentations to the Legal Commission of the IBC responsible for drafting the UDHGHR (1997). The bulk of the consultation on this declaration was written, however. (UNESCO, *Birth of the Universal Declaration on the Human Genome and Human Rights*, 54 and 98.)

<sup>63</sup> The cost of participating in such meetings is borne by UNESCO, as per the statutes of the IBC: “UNESCO shall bear the expenses of the participation of specialists in connection with hearings requested by the IBC.” (UNESCO, “Statutes of the IBC,” 3.)

<sup>64</sup> UNESCO, “Public Hearings Day on Human Genetic Data,” 1.



country researchers, interest groups and insurance and pharmaceutical companies, were discussed by a broad audience, comprising the drafting group and some thirty observers attending in a personal capacity or on behalf of member states or other IGOs (including WHO). The drafting group duly took these discussions into consideration at its subsequent meeting.<sup>65</sup>

Various hearings took place during the drafting of the UDBHR (2005). Before even the first meeting of the drafting group, the IBC held an extraordinary session in order to gauge the opinions of “the actors concerned” on the scope and structure of the proposed declaration (namely other IGOs, organisations such as the World Medical Association and HUGO and national bioethics committees).<sup>66</sup> At its eleventh session in August 2004 representatives of different “religious and spiritual perspectives” gave presentations. This meeting also hosted a public discussion and was attended by more than 250 participants from 80 countries.<sup>67</sup> In 2005, national and regional expert consultations were held in several states, including Argentina, Mexico and Indonesia, as part of the “Ethics Around the World” project (see 6.2.1).<sup>68</sup> Pharmaceutical companies were invited to make contributions at various sessions, but were “quite quiet.”<sup>69</sup>

In terms of formal negotiations, non-state actors took part to a limited degree. Only eleven NGOs attended the UDBHR IGE meetings.<sup>70</sup> The Provisional Rules of Procedure, published in February 2005, stated, “All plenary sessions shall be held in public, unless the Meeting decides otherwise.”<sup>71</sup> The meetings were classified as category II, however, meaning that all observers had to be approved by the Executive Board. The Board

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<sup>65</sup> Ibid, 1 and Annex II, 3-5.

<sup>66</sup> UNESCO, “Extraordinary Session of the IBC: ‘Towards a Declaration on Universal Norms on Bioethics’,” 1, 3, 4 and 6.

<sup>67</sup> UNESCO, “Towards a Declaration on Universal Norms on Bioethics,” PowerPoint presentation; UNESCO, “Eleventh Session: IBC,” 1.

<sup>68</sup> UNESCO, “Towards a Declaration on Universal Norms on Bioethics,” PowerPoint presentation; UNESCO, “Report by the Director-General on the Drawing Up of a Declaration on Universal Norms on Bioethics,” 4. It was hoped that meetings would also be held in the African and Arab region, but this did not prove possible within the time available. (Interview with F\_01.)

<sup>69</sup> Interview with F\_01.

<sup>70</sup> UNESCO, “First Intergovernmental Meeting of Experts: List of Participants,” 15 and “Second Intergovernmental Meeting of Experts: List of Participants,” 17-18.

<sup>71</sup> UNESCO, “First Intergovernmental Meeting of Experts: Provisional Rules of Procedure,” 3.

approved the list of invitations in September 2004, fully five months before the rules of procedure were made public.<sup>72</sup> The only UN agencies (other than UNESCO) to attend the meetings were the World Trade and World Health Organizations,<sup>73</sup> although IGOs had other opportunities to feed into the UDBHR, through the UN Inter-agency Committee on Bioethics. At the Committee's third meeting in June 2004, participants "reiterated their full support for the drawing up of a declaration providing a universal ethical framework in the field of science and technology," but wished to clarify the scope of the declaration.<sup>74</sup> Their concerns on this front were carried through to the fourth meeting, in December 2004, when some committee members commented that the declaration "should not go beyond the field of competence of UNESCO" (see also 6.3.2).<sup>75</sup>

The low attendance of non-state actors at formal negotiations notwithstanding, the Director-General highlighted at the first UDBHR IGE meeting in April 2005 the "transparent and participatory nature of the elaboration process."<sup>76</sup> Similarly, at the 2005 General Conference, member states expressed satisfaction that the drafting process had been open, involving a wide range of actors.<sup>77</sup> Despite all the written and verbal consultations, however, these opinions were not necessarily shared outside UNESCO. In a September 2005 special issue of *Developing World Bioethics* devoted to the draft UDBHR, John Williams (then Director of Ethics at the World Medical Association) was critical of the fact that the version of the declaration approved by the June IGE meeting

<sup>72</sup> Personal e-mail, 16 March 2005. Thus it was not possible for the IGE meetings to be observed in person.

<sup>73</sup> UNESCO, "First Intergovernmental Meeting of Experts: List of Participants," 14 and "Second Intergovernmental Meeting of Experts: List of Participants," 16.

<sup>74</sup> UNESCO, "Information Meeting with IGBC on the Progress of the Elaboration of a Declaration on Universal Norms on Bioethics," 2.

<sup>75</sup> UNESCO, "Sixth Meeting of the IBC Drafting Group for the Elaboration of a Declaration on Universal Norms on Bioethics," 1.

<sup>76</sup> UNESCO, "First Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics: Final Report," 1.

<sup>77</sup> UNESCO, "Address by Mr Koïchiro Matsuura, Director General of UNESCO," twelfth session of the IBC, Tokyo, Japan, 15-17 December 2005, DG/2005/201, 2. In a separate report, the Director-General attributed this transparency partly to the availability of relevant documents on the UNESCO website, which he said made the drafting process open to "the greatest possible number." (UNESCO, "Report by the Director-General on the Drawing Up of a Declaration on Universal Norms for Bioethics," 1 and 7.) Similarly, at the January 2005 IBC meeting, the chair of the UDBHR drafting group, Justice Kirby, declared that all documentation concerning the draft declaration would be put on the UNESCO website, under a principle of transparency. (IBC meeting, Paris, 28 January 2005, personal observation.) Whilst the Director-General's statement might be true, it does not necessarily follow that consultation through the website was sufficient. Aside from the bias this might have entailed towards those with easy access to the internet (discussed further at 6.2.1), several stakeholders in Kenya and South Africa had simply not thought, or had not had time, to look at the UNESCO website in connection with genetics and bioethics. (Interviews with SA\_03 and SA\_27 and informal conversations with staff at the KEMRI-Wellcome Trust Collaborative Programme in Kilifi, Kenya.)



had not been through the same broad consultation procedures as earlier drafts.<sup>78</sup> Some South African interviewees expressed concern about the entire process. One ethicist commented:

You don't just want a faceless committee designing this. Maybe some of them do have experience, but why not make it an open process? What would be the problem with that? Why have they not involved individuals with expertise and wide recognition or standing in the international bioethics community?<sup>79</sup>

Another said that the initial draft of a document such as the declaration should be drawn up by experienced committees, but then made open for public scrutiny "in such a way that people know about it and it's readily accessible."<sup>80</sup> For some interviewees, these people would necessarily include those potentially vulnerable research subjects that the declaration seeks to protect. One asked:

The declarations have made decisions for the international public, but which international public? I mean, for me, the research participants in South Africa are the rural research participants on the ground. How much have they had a say in terms of the declaration? Have we had our tribal leaders being involved in these discussions?<sup>81</sup>

As discussed further in the second part of this chapter, many potential contributors from Kenya and South Africa (bioethicists, scientists, policy-makers and civil society representatives, as well as research subjects) were not among those invited by the IBC, through its various international consultations, to comment on the draft texts. This has implications for the legitimacy of the declarations, in that people are less likely to pay them due attention if they believe them to have been drawn up covertly.

### 5.1.3 Relative Influence of state and non-state actors

Although the texts of the UNESCO declarations were drawn up by the IBC and commented on by several non-state actors, decisions on the final drafts and whether they

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<sup>78</sup> Williams, "UNESCO's Proposed Declaration – A Bland Compromise," 211.

<sup>79</sup> Interview with SA\_25.

<sup>80</sup> Interview with SA\_19.

<sup>81</sup> Interview with SA\_17 (quoted). K\_07 and SA\_25 made similar comments.

should be adopted ultimately lay with member states.<sup>82</sup> This was not without its problems. For the UDBHR (2005), for example, some countries sent civil servants or embassy representatives to the IGE meetings rather than bioethicists (delegate expertise is discussed further in 5.2.1). A member of the Bioethics Programme said that this meant that what had been put together logically and rationally by a body of non-state experts, the IBC, was then overridden in a political process by inexperienced state representatives.<sup>83</sup> He described the relationship between experts and states as “always a tension,” giving the following example of how it can lead to weak compromises:

We had an article on risk management, which was in fact arguing the precautionary principle without mentioning it. And then some of the delegations, they took the whole text out and they changed it for a very general text, which has been accepted. So now the text there is an open door, it's just a generality.<sup>84</sup>

Another illustration of this tension is provided by the debate at the January 2005 joint IGBC and IBC meetings over whether the UDBHR (2005) and implementation guidelines for the IDHGD (2003) were to include reporting mechanisms, under which states would have to periodically inform UNESCO about measures taken to realise the declarations. In an informal conversation, a member of the IBC remarked that the Committee would try to include more concrete obligations than in the past, but that this was a “shot in the dark,” as these would probably get watered down by states.<sup>85</sup> Describing the room as having a

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<sup>82</sup> Similarly, it was states that determined whether they should be drafted in the first place. When the IBC presented its report on the possibility of elaborating an instrument on bioethics to the IGBC, the latter was reminded that this was merely a “feasibility study” and that it was for states to decide, at the General Conference, whether the elaboration should go ahead. (UNESCO, “Report of the Third Session of the IGBC,” 8.)

<sup>83</sup> Interviews with F\_01 and UK\_02. Howard Wolinsky captures this process pithily, describing the UDBHR negotiations as “a dance between government and bioethics groups.” (Wolinsky, “Bioethics for the World,” 355.) One attendee at the April and June IGE meetings observed that, although there were several non-state actors present, they had fewer opportunities to speak than the state representatives, even though they perhaps knew more about the subject matter. (Interview with UK\_02.) By contrast, in an informal conversation at the January 2005 meetings, a former member of the IBC, who had helped to draft the 1997 and 2003 declarations, voiced ambivalence with regard to observers, particularly those representing interest groups. Some had useful things to say, he said, but others were determined to get their point across, whether or not it was relevant to the discussion at hand.

<sup>84</sup> Interview with F\_01. An attendee at the April and June meeting corroborated the tension that F\_01 identified. (Interview with UK\_01.) The following anecdote offers a further illustration of this tension. During the January 2005 IGBC meeting in Paris, a member of the IBC wanted to make a comment. Before he could do so, however, a member of the IGBC complained that this would be inappropriate and that any such comments should be voiced only within the joint meeting between the two committees later in the week. He rounded off his objection with the words, “In my opinion, governance is about government.” (IGBC meeting, Paris, 24 January 2005, personal observation.)

<sup>85</sup> Informal conversation, 26 January 2005.



metaphorical Red Sea down its middle that the meeting would have to try to bridge, Justice Kirby (chair of the UDBHR drafting group) told those assembled that there would be some issues, such as the reporting mechanism, on which the two committees would take different views. The IBC members were independents whilst the IGBC representatives were not, he said; each should fulfil their function, but it would be the states that would make the final decisions on such matters, through the political processes of UNESCO. The states duly decided that it would be inappropriate to include any such mechanism in the UDBHR.<sup>86</sup> (The implications of the reporting debate for the effective implementation of the declaration are discussed at 6.2.3.)

#### **5.1.4 Relations between international and national levels**

3.5.2 considered Held's claim that 'chains of delegation' have rendered IGOs inaccessible. The secretariat of the Bioethics Programme, despite having a small staff, takes great pains to act transparently. To this end, a plethora of information on the Programme's activities is freely available on the UNESCO website (to those with internet access). When it comes to actively distributing materials to member states, however, there can be problems. A member of the Programme explained that it cannot be sure whether information is always getting to the most appropriate government departments, because UNESCO deals primarily with ministries of education, even though these might not perhaps be the most natural ports of call with regard to bioethics and genetics.<sup>87</sup> In both Kenya and South Africa, some government officials working in these areas were unaware of the declarations at the time of fieldwork.<sup>88</sup> One of them, from South Africa's Department of Science and Technology, corroborated the difficulties described by the Bioethics Programme representative:

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<sup>86</sup> UNESCO, "Second Intergovernmental Meeting of Experts: Final Report," 7-8.

<sup>87</sup> Interview with F\_01.

<sup>88</sup> Interviews with K\_20, K\_21, SA\_28 and SA\_31.

Basically we don't track the UNESCO processes directly from the department, which is something that made me think that we should do more, because the UNESCO relationship is owned by our Department of Education and they hadn't briefed us or asked us for assistance in this particular declaration.<sup>89</sup>

It seems that these difficulties stem from incoherencies between international and national levels rather than lack of willing. UNESCO hopes that as more national bioethics committees are established chains of communication will become clearer (see 6.2.1).

### **5.1.5 Global Genomics Initiative: an Improvement?**

The sections above have described systems of representation and accountability within UNESCO, a traditional IGO, for the elaboration of declarations on genetics and bioethics. This section examines whether the multisectoral GGI, if established, might prove a more equitable governance model, in terms of relations between North and South and between state and non-state actors. Although news to many of them, the plans for the GGI generated a considerable amount of enthusiasm among interviewees.

#### **5.1.5.1 Leadership from the South**

Like Held and UNDP, those at the Toronto Joint Centre for Bioethics who have proposed the GGI argue that the capacity of developing countries to participate effectively in international negotiations needs to be enhanced.<sup>90</sup> TJCB envisions that the GGI would enable these countries to assume leadership in "driving the agenda for health equity."<sup>91</sup> In a 2001 article in which they proposed their early, commission-based version of the GGI, Abdallah Daar and Peter Singer wrote,

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<sup>89</sup> Interview with SA\_31.

<sup>90</sup> Dowdeswell, Daar and Singer, "Bridging the Genomics Divide," 3.

<sup>91</sup> Dowdeswell *et al*, op cit, 139.



The voices of those in developing countries must be heard as the health biotechnology revolution unfolds. Those protesting in Genoa are not the ones who are sick in Africa. We need to develop a mechanism to tap the views of opinion leaders in developing countries on important policy questions and in real time.<sup>92</sup>

In its various publications, TJCB does not actually articulate how it would recruit such leaders. Of the 45 people in Kenya and South Africa asked about the GGI, including geneticists, bioethicists, policy-makers, civil society representatives and those involved in the commercialisation of biotechnology, only half were aware of the proposed network and none had definitely been asked to join.<sup>93</sup> Given that TJCB locates legitimacy in including those affected by a given issue (if indeed opinion leaders truly represent the sick), that it has involved in its planning few of those with a stake in the “health biotechnology revolution” does not bode well. Thus were the GGI to be established, more effective recruitment from the South would be necessary. How this might be achieved is discussed in Chapter 7.

Some South African interviewees saw the goal of leadership from the South as central to the proposed network’s legitimacy. They described how norms have in the past been imposed on developing countries as *faits accomplis*, thus the engagement of the South in “true interaction” would be highly significant.<sup>94</sup> Others foresaw difficulties, however. According to one Kenyan scientist, because of the lack of technical capacity in developing countries, potential leaders are scarce and have often moved to northern institutions. On the plan to garner southern leadership he said, “I think in some ways that has to go hand in hand with building the capacity for people to actually be able to work within their own environments in the South” (which would be one of the proposed GGI’s aims, as it is of the UNESCO declarations).<sup>95</sup> Another participant would want to see wider participation from activist groups from the North, which he thought needed to find better ways of

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<sup>92</sup> Singer and Daar, “Harnessing Genomics and Biotechnology to Improve Global Health Equity,” 89.

<sup>93</sup> Only bioethicists who serve on national committees or who contribute to policy or training at national or regional level are included in this sample. Of the 45, 22 were aware of the GGI, 22 were not and one was unsure. Two had been on the 2002 executive course in Nairobi and were still in contact with TJCB and two were unsure whether they or their institution had been asked to become involved with the proposed GGI. Unfortunately it was not possible to interview two people who, from perusals of websites and literature, it seems would almost certainly have been involved.

<sup>94</sup> Interviews with SA\_30 (quoted), SA\_21 and SA\_24.

<sup>95</sup> Interview with K\_08.

engaging with the South. Although he saw the proposed GGI as “critical in moving the agenda for capacity building,” he predicted that ensuring equitable relationships would be challenging and that ‘the South’ would not speak with a unified voice: “Internally there would be multiple sectoral interests with diverse agendas.”<sup>96</sup>

#### **5.1.5.2 Relations between state and non-state actors**

The GGI, should it come to fruition, would be a multisectoral network, involving experts from governments, civil society, the private sector and research institutions. When asked if they would be interested in joining such a network, people from all these sectors in Kenya and South Africa voiced enthusiasm (both those who had come across the GGI previously and those who had not).<sup>97</sup> Key figures in the implementation of the South African National Biotechnology Strategy were particularly eager. One said, “Great, wow... That would be really interesting to find out more about,” while another thought that the network sounded “extremely useful” for both South Africa and Africa in general, thus sensing an almost “moral obligation” to participate in or support it.<sup>98</sup> Several scientists were also keen. One commented, “It seems a very sensible way to go to make a real difference” and another wanted to visit the TJCB website to find out more. A third thought the GGI might provide some much needed direction on issues such as gene patenting.<sup>99</sup>

Many participants particularly welcomed the proposed mixed membership of the GGI. One said, “The more interested parties contribute to the work and the more multisectoral it is, the more likely it is to happen.”<sup>100</sup> Some saw the network as potentially a good way to

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<sup>96</sup> Interview with SA\_13.

<sup>97</sup> Of the 45 participants in Kenya and South Africa asked about the GGI, 37 were supportive, three were ambivalent and two did not indicate a position. Three were unsupportive, on the grounds that it was in fact an industrialised world rather than global initiative, that it was unlikely to end in tangible goals and that it would probably become too bureaucratic to deal with urgent issues. (Interviews with SA\_20, SA\_07 and K\_11 respectively.)

<sup>98</sup> Interviews with SA\_26 and SA\_28 respectively. At the other extreme, some might consider it almost a moral obligation *not* to support the GGI, seeing the proposed network as a potentially fatal distraction from more urgent needs.

<sup>99</sup> Interviews with SA\_21 (quoted), SA\_27 and K\_03.

<sup>100</sup> Interview with SA\_15.



exchange information and ideas. A private genetics research company in South Africa, for example, would join the GGI in order to share its products and technologies with companies in other countries facing the types of barriers it had already overcome.<sup>101</sup> Just as some interviewees believed the GGI would derive legitimacy from its planned southern leadership, others saw the multisector approach as a fundamental component. Hence it would need buy-in from people from all walks of life.<sup>102</sup> A Kenyan scientist thought that involving civil society would be essential, whilst a civil society representative hoped the network might encourage scientists to be more vocal in policy-making.<sup>103</sup> One person sounded a note of caution. A combination of public and private partners was a good idea, she said, but the network would have to be above the individual interests of its members.<sup>104</sup> In other words, they would have to behave as Rischard's 'global citizens' (see 3.5.2).

This analysis has shown that there would be a demand for a GGI-like network among stakeholders in genetics and bioethics in Kenya and South Africa, should they be made more aware of the possibility. One interviewee captured this sentiment as follows: "It is a great initiative. They should bring this to us, disseminate it here so that we know."<sup>105</sup> A network structure might represent an improvement on the IGO model of participation, with state and non-state actors collaborating as equals, unlike in the two stage process at UNESCO that sees states making final decisions on the work of non-state experts. Should this structure also be 'flatter' than traditional IGOs, as Rischard claims such networks would be, it might also avoid some of the problems faced by UNESCO in terms of chains of communication.

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<sup>101</sup> Interviews with K\_13 and SA\_06.

<sup>102</sup> Interview with SA\_32.

<sup>103</sup> Interviews with K\_08 and K\_14.

<sup>104</sup> Interview with K\_26.

<sup>105</sup> Interview with K\_19.

### 5.1.5.3 Institutional legitimacy

The GGI, if constituted, would be an independent body. This raises the question of what rights it would have to represent the global populace, particularly with regard to the formulation of universal norms and principles. UNESCO claims legitimacy for its declarations by virtue of their falling under the UN system. One interviewee concurred with UNESCO on this point and another said, “Well the UN has staying power, I’ll say that for it... I think the UN’s a good place to start if you want such an initiative to last.”<sup>106</sup> Several participants did not see the UN as offering inherent legitimacy or effectiveness, however; thus they did not think the proposed network’s independence would be a problem *per se*. Rather, its legitimacy would depend on what it did and whether it involved the right people, those “at the sharp end of doing things.”<sup>107</sup> One ethics committee member made the following comment, based on his perceptions of international meetings: “You can invite people from Africa who might not be the right people, you just have faces. As I say that always worries me.”<sup>108</sup> TJCB also envisages the GGI garnering legitimacy through being underpinned by governments. A South African participant described why this might be important in an African context: “In many African countries I certainly get the impression that if things don’t have the stamp of approval from government then they don’t go anywhere... A lot of individual initiatives just fall off the table because people don’t follow the right channels and so forth.”<sup>109</sup> As shown in the second part of this chapter, however, just as legitimacy through the UN cannot be assumed, nor can legitimacy through the state.

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<sup>106</sup> Interviews with SA\_37 and K\_17 (quoted) respectively.

<sup>107</sup> Interviews with SA\_19 (quoted), K\_18, SA\_10 and SA\_16.

<sup>108</sup> Interview with SA\_10.

<sup>109</sup> Interview with SA\_27.



## 5.2 NATIONAL LEVEL<sup>110</sup>

5.1 explored how decisions are made at international level. The chapter now turns to the national level, in terms of how those representing states at international level are selected and on what their negotiating positions are based. 53 interviewees in Kenya and South Africa unconnected with UNESCO were asked to what extent they knew the three genetics and bioethics declarations. Thirty had come across them, of whom eighteen only peripherally.<sup>111</sup> This would imply that a majority of potential stakeholders were not included in the elaboration process at national level.

### 5.2.1 Delegate selection and expertise

The Director-General of UNESCO reported in 2002, "Despite the ever greater importance of bioethics worldwide, this discipline is still too often the preserve of a handful of specialists."<sup>112</sup> As shown by the make-up of the IBC (see 5.1.2.1), UNESCO considers people from various backgrounds to have expertise in bioethics. Reflecting this, the UDBHR was drafted as a "practical application" document rather than an academic one.<sup>113</sup> At the June 2005 IGE session charged with finalising this declaration, the Director-General thanked member states for sending "strong, quality delegations."<sup>114</sup> The chief Kenyan and South African delegates to this meeting were both scientists with experience of applying bioethical principles in their work. The Kenyan expert was selected as his

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<sup>110</sup> The data analysed below relate almost entirely to the 2005 UDBHR, reflecting the timing of fieldwork, which took place just before and after the declaration was adopted.

<sup>111</sup> There were 64 participants in total from Kenya and South Africa, six of whom had UNESCO connections. Of these six, three were unaware of the declarations before being invited to become involved with UNESCO activities, including two IGE representatives. Five participants were not asked about the declarations, because the interviews were on specific topics, such as public awareness and community engagement programmes.

<sup>112</sup> UNESCO, "Report by the Director-General on Action to be Taken in the Light of the Round Table of Ministers of Science on Bioethics (22-23 October 2001)," 5. The editors of the 2005 *Developing World Bioethics* special issue on the declaration had an entirely different view: "Perhaps worthy of debate within UNESCO at this stage, is its very approach to bioethics. Bioethics, as we understand it, is an academic discipline and not a playground for government appointed politician-experts to muse in an inconsequential and arguably not very sophisticated manner about ethics." (Landman and Schüklenk, "From the Editors," vi.)

<sup>113</sup> UNESCO, "First Intergovernmental Meeting of Experts: Final Report," 3-4.

<sup>114</sup> UNESCO, "Second Intergovernmental Meeting of Experts: Final Report," Annex II, 1. Again, a different view is expressed in *Developing World Bioethics*. John Williams sardonically refers to those who attended this meeting as 'experts' throughout his paper. (Williams, op cit.)

country's UNESCO Chair in Bioethics. He was accompanied to the June meeting by the Kenyan deputy permanent delegate to UNESCO (based in Paris) and to the previous session in April by a member of Kenya's National Council for Science and Technology. His South African counterpart, a geneticist, was appointed by the Minister of Education. She attended only the June meeting, although the South African deputy permanent delegate was at both sessions. The Kenyan IGBC representatives at the January 2005 meetings were both from the National Commission for UNESCO.<sup>115</sup>

Although the majority of interviewees in Kenya and South Africa were unfamiliar with the declarations, several had strong opinions about who should be representing them at international negotiations in general. Two Kenyan participants did not believe delegation was well managed. The first, a civil society actor, could find no consistency from one meeting to the next: "The people who represent the government—today it's this person, another month it's somebody completely different from another ministry."<sup>116</sup> The second also saw the appointment process as capricious, such that ill-informed government officials attend international meetings at short notice, with little time to absorb the relevant facts and statistics. She asked, "Who is representing my views as a geneticist?"<sup>117</sup> That such perceptions exist, even if false, could be damaging to the legitimacy of the declarations.<sup>118</sup> If people are concerned that those who did the drafting were not sufficiently expert to do so, they may have little respect for the declarations as valid normative instruments.

As in Kenya, South African participants were of the opinion that representatives at international negotiations need to have a certain level of expertise. Particularly with regard to the bioethics declaration (UDBHR, 2005), however, they differed on where the requisite

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<sup>115</sup> Interviews with K\_01 and SA\_23; UNESCO, "First Intergovernmental Meeting of Experts: List of Participants," 1 and 9, "Second Intergovernmental Meeting of Experts: List of Participants," 1 and 10 and UNESCO, "Fourth Session, IGBC: Provisional List of Participants," 5.

<sup>116</sup> Interview with K\_14.

<sup>117</sup> Interview with K\_26.

<sup>118</sup> There was in fact consistency of representation in the case of the UNESCO declarations in that the UNESCO Chair in Bioethics attended both meetings. Moreover, he had plenty of communication with those from the National Commission who had attended the January 2005 meetings and were coordinating input into the Kenyan negotiating position (see 5.2.2). (Interviews with K\_01 and K\_16.)



expertise lay. Some of those who conduct genetic research involving human subjects felt that experience 'at the coalface' was important. This would furnish an understanding of the intricacies of obtaining informed consent, for example.<sup>119</sup> One commented, "I think it's very dangerous to have a group of academics putting it [the UDBHR] together when they don't understand what the issues are on the ground, because they can dream up things that are wonderfully ethically sound, but are totally impractical."<sup>120</sup> A long-standing member of a research ethics committee also thought that practical experience was important, but in terms of ethical review rather than research. Having seen some registers of those involved in UNESCO's bioethics activities, he expressed concern that very few of the people listed had sat on an ethics committee, remarking, "I found one South African representative that I know has no bioethics research experience on any committee in this country, but is regarded as an expert. And that worries me."<sup>121</sup> Others thought that those with a background in the philosophy of bioethics had a vital role to play, because they have been trained in the logical construction of arguments.<sup>122</sup> One said of the UDBHR, "I can't see that there were bioethicists involved in the drafting of that thing... I think it's unusable."<sup>123</sup> The tensions between these different positions were articulated by a prominent actor in South African bioethics:

So what does it mean to be 'a bioethicist'? Should everybody who calls him or herself a bioethicist be consulted? Bioethics is a contentious field populated by scholars, professionals and others from many disciplines, not all of whom have had an adequate training or experience. So whose voices should be heard?<sup>124</sup>

In reality, on being asked who should have put the declarations together, most participants thought a range of people essential, including scientists, ethics committee members and philosophically trained bioethicists, but also government representatives, legal experts, civil society actors and those with previous experience of international

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<sup>119</sup> Interviews with SA\_12, SA\_20 and SA\_21.

<sup>120</sup> Interview with SA\_21.

<sup>121</sup> Interview with SA\_19.

<sup>122</sup> Interviews with SA\_08 and SA\_16.

<sup>123</sup> Interview with SA\_16.

<sup>124</sup> Interview with SA\_09.

negotiations.<sup>125</sup> One government official who has attended many such negotiations commented, “The people who are prepared to explore the art of the possible are the people we should have in the room,” the ‘art of the possible’ signifying compromise.<sup>126</sup>

### 5.2.2 Wider Input

While to include at international meetings a range of stakeholders from each state as diverse as that listed above might prove impractical, governments could seek the advice and opinions of such actors in deciding what views their representatives should take to the negotiating table. For one interviewee, whether there had been wide consultation on the draft UDBHR (2005) was more important than who actually made the final decisions: “I think the process is key, rather than just the people.”<sup>127</sup> Kenya’s role in the negotiation of this declaration was coordinated by the National Commission for UNESCO. In formulating its position, the Commission garnered opinions from various people it considered experts, namely members of its own Natural Sciences and Human and Social Sciences Committees and officials from the Ministry of Justice and Constitutional Affairs, the Kenya Medical Research Institute and the National Council for Science and Technology.<sup>128</sup> These expert views were sometimes overruled by the permanent delegates to UNESCO in Paris (who are members of the African Group), in consultation with the Ministry of Foreign Affairs, as to what the official negotiating position should have been.<sup>129</sup> Nevertheless, the chief Kenyan IGE representative carried out a similar process to that of the National Commission, in order to be able to present a “Kenyan position” at the meetings.<sup>130</sup> Thus the tension between experts and states identified at international level seems to have been mirrored somewhat at national level. There were no broader

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<sup>125</sup> Interviews with SA\_08, SA\_10, SA\_14, SA\_15, SA\_21, SA\_24, SA\_30, SA\_31, SA\_32, SA\_33 and SA\_35. This question was only asked in South Africa.

<sup>126</sup> Interview with SA\_31.

<sup>127</sup> Interview with SA\_15.

<sup>128</sup> Interviews with K\_02, K\_13 and K\_16.

<sup>129</sup> Interviews with K\_16 and K\_30.

<sup>130</sup> Interview with K\_16. K\_02 corroborated that the chief IGE delegate had been active in formulating Kenya’s negotiating position.



consultations with scientists, civil society groups or the general public in Kenya. On this point, the UNESCO Chair of Bioethics said:

No, there is not such a thing. Actually that's an issue which myself and another colleague who also attended the April meeting raised when we came back, in our report: that before any of those meetings take place, there must be meetings to agree on our stand and formulate our agenda. And that one has not taken place.<sup>131</sup>

There was less discussion of the draft declaration in South Africa than in Kenya. The only input, albeit of a limited fashion, came from the South African Medical Association's Human Rights Law and Ethics Committee.<sup>132</sup> A quote from a senior member of a university bioethics department serves to illustrate the paucity of consultation: "You know, UNESCO has never contacted me with anything, so it's basically finding out from our bioethics circles as to what's happening in UNESCO and then looking up things on our own. But I have never been contacted by UNESCO."<sup>133</sup> The chief IGE delegate was thus left with what Chasek and Rajamani would term a 'hollow mandate' as to how she was to represent South Africa. She commented, "In hindsight, I attended the meeting poorly equipped to voice the opinions of the country."<sup>134</sup>

In both Kenya and South Africa, input into the negotiating positions for the UDBHR (2005) on the part of government officials appears to have been curtailed by lack of communication within and between departments. At the time of fieldwork, both the Kenyan National Commission for UNESCO and the National Council for Science and Technology (NCST) fell under the Ministry for Education, Science and Technology. A member of the Commission described those at NCST as "very close partners" and, indeed, as mentioned in the previous section, an NCST representative attended the April IGE meeting.<sup>135</sup> Nevertheless, two members of NCST, who deal with biotechnology and bioethics respectively, did not know of the declarations. The former said that the connection with

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<sup>131</sup> Interview with K\_01.

<sup>132</sup> Interviews with SA\_16 and SA\_23.

<sup>133</sup> Interview with SA\_17.

<sup>134</sup> Interview with SA\_23.

<sup>135</sup> Interview with K\_16.

UNESCO had never been clear, the latter that he had never heard of UNESCO engaging in any kind of bioethics activities.<sup>136</sup> Equally, the chief delegate to the IGE meetings appeared to be unaware of the ethical guidelines NCST had recently produced (see 6.3.2).<sup>137</sup> Despite the various connections, then, it seems that key information was not shared within and between the National Commission for UNESCO and NCST. South Africa faced a similar problem, but between government units rather than within them, as it has separate departments for education and for science and technology. As explained at 5.1.4, UNESCO headquarters deals directly with the Department of Education (where the South African National Commission for UNESCO is housed), which did not consult with the Department of Science and Technology with regard to the UDBHR. A member of the latter complained, "Different government departments are not interacting enough, so that there is kind of an information gap between the different ones and not enough collaboration."<sup>138</sup>

The lack of input into the declarations among non-state actors in Kenya and South Africa may be partly attributable to a low level of engagement in genetics and bioethics policy-making generally, among both scientists and the general public. Although several geneticists were sceptical of the declarations' legitimacy because they felt their views had not been adequately represented during negotiations, they were hesitant to involve themselves in policy-making. Their priorities are research and teaching, hence they have little time to spare for other endeavours, particularly given the small size of the scientific community in each country.<sup>139</sup> With regard to public involvement in policy-making, the picture is somewhat mixed in both Kenya and South Africa. In the former, Ministry of Health guidelines for research into HIV/AIDS vaccines, published in 2005, were developed in consultation with NGOs, community representatives, faith-based organisations and professional societies (as well as government officials, researchers and healthcare

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<sup>136</sup> Interviews with K\_20 and K\_21 respectively. K\_21 knew about the proposed regional centre at Egerton University, however (see 6.3.2.3), but had not realised it was a UNESCO initiative.

<sup>137</sup> Interview with K\_01.

<sup>138</sup> Interview with SA\_26.

<sup>139</sup> Interviews with K\_03, K\_05, SA\_03, SA\_04, SA\_07, SA\_21, SA\_30 and SA\_35.



workers).<sup>140</sup> These guidelines notwithstanding, several interviewees were of the opinion that there is little public participation in bioethics and genetics matters in Kenya, with discussions tending to be confined to certain circles.<sup>141</sup> In South Africa, the mechanisms are in place for people to make comments on impending regulations or legislation.<sup>142</sup> It is mostly activist groups that take advantage of these, however, rather than the public at large.<sup>143</sup> The problem is that public understanding of ethics and genetics is low.<sup>144</sup> At the time of fieldwork, a recent survey had shown that South Africans were “woefully ignorant” about biotechnology.<sup>145</sup> One geneticist commented that “they wouldn’t know what to ask.”<sup>146</sup>

To address this situation, the Department of Science and Technology in South Africa runs a Public Understanding of Biotechnology programme, which engages in a wide range of activities, such as drama presentations, exhibitions, science fairs and supporting schools’ curricula.<sup>147</sup> The African Genome Education Initiative also has a mandate to increase public knowledge about genetics.<sup>148</sup> Some Kenyan interviewees intimated that public education would be useful in their country too, to demystify the research process and enable people to engage with ethics and genetics issues.<sup>149</sup> Two organisations work in this area. The African Biotechnology Stakeholders Forum endeavours to provide credible, balanced and up-to-date information on biotechnology, while Biosafety News, a newspaper and website, aims to act as a bridge between scientists and the general public.<sup>150</sup> With regard to the declarations, a representative from the latter said, “At the moment, even if we carried something like that on our ‘paper, I think people would be like,

<sup>140</sup> Ministry of Health, *Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines*, vii.

<sup>141</sup> Interviews with K\_01, K\_02, K\_14, K\_18, K\_19, K\_21 and K\_26.

<sup>142</sup> Interviews with SA\_04, SA\_10, SA\_15, SA\_16, SA\_24, SA\_29 and SA\_33.

<sup>143</sup> Interviews with SA\_10, SA\_16, SA\_21, SA\_27 and SA\_33.

<sup>144</sup> Interviews with SA\_21, SA\_27, SA\_30 and SA\_33.

<sup>145</sup> Interviews with SA\_26 (quoted) and SA\_29.

<sup>146</sup> Interview with SA\_27.

<sup>147</sup> Interviews with SA\_26 and SA\_29.

<sup>148</sup> Interview with SA\_11.

<sup>149</sup> Interviews with K\_17, K\_19 and K\_25.

<sup>150</sup> Interviews with K\_10 and K\_14 respectively.

Whoa, what is this?’ I can tell you that for sure.”<sup>151</sup> (What actually constitutes informed public participation in decision-making is discussed further in Chapter 7.)

It is important to take note of these low levels of input—into the declarations directly and into genetics and bioethics policy generally—for two reasons. Firstly, the declarations themselves call for broader education and engagement around genetics and bioethics.<sup>152</sup> Secondly, if the declarations are to be respected and implemented, they will need a wider support base than was evident during their negotiation. This was recognised by participants in the IGE meetings for the UDBHR in 2005 from both countries. The chief Kenyan delegate thought it necessary to share the declarations beyond those few who had attended the international negotiations. “Otherwise,” he remarked, “we go to those meetings, we keep quiet, that’s the end of it.” At the time of fieldwork, he was planning to hold a meeting to raise awareness about the declaration and to discuss how it might be domesticated, to which he would invite “the experts, the communities and interested parties.”<sup>153</sup> His South African counterpart likewise commented that the declaration’s principles needed to be promoted among the general public:

We all have a responsibility to ensure—not just as scientists, but as members of the general public—that this sort of best practice is part and parcel of the very core of our moral values. It doesn’t matter that you only try to aspire to these when you’re doing genetic research, it should be core principles and perhaps we should have some education around it.

In order to achieve this, she said, the Department of Science and Technology and the Department of Health would have to work in partnership with the Department of Education (which had commissioned her participation in the UNESCO negotiations) at national and provincial levels, within an overall structural framework (see 6.3.2.2). The expertise of “someone well-versed in South African law” would also be required, to give guidance on how the declaration’s articles could best be implemented “at a general public level.”<sup>154</sup> A member of the Department of Science and Technology outlined how the potential impact

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<sup>151</sup> Interview with K\_14.

<sup>152</sup> The relevant articles are: UDHGHR, articles 20, 21 and 23; IDHGD, articles 6 (a), 23 (a) and 24; and UDBHR, articles 18 (2 and 3), 19 (d), 22 (1) and 23 (1).

<sup>153</sup> Interview with K\_01.

<sup>154</sup> Interview with SA\_23.



of the declarations on South African biotechnology policy had already been lessened, because these connections had not been made earlier. He said:

Bioethics is obviously a key issue in growing a biotechnology sector, so it's very important. It probably would have been useful if, at an early stage, we could have grappled with these things and taken them on board. Not that we haven't, but we've now developed our own thinking... well, almost in the absence of the UNESCO documents.<sup>155</sup>

For these endeavours to bear fruit, the Kenyan and South African National Commissions for UNESCO and their associates will have to find ways to overcome the difficulties previously faced in garnering wide input into genetics and bioethics policy, namely poor communications within government, reluctance among scientists to take time out from their core research and teaching activities and low public understanding of the issues at hand. Some responses from interviewees hint at how they might succeed in this. A long-standing member of a Kenyan ethics committee, making a general comment, described what could be achieved by engaging with government: "Our policy-makers here are fairly open, yes, they are quite open to new ideas. But as I say, you just need to empower them with the information, they need to know what you are talking about."<sup>156</sup> (Chapter 6 discusses sensitisation further; see 6.3.2.1.) With regard to scientists, two interviewees suggested that they would be more inclined to contribute to an initiative if they could see that the people behind it were serious and that it was going to translate into concrete outputs.<sup>157</sup> In terms of the general public, a member of the Africa Genome Education Initiative said that the declarations are important as a "global signpost," but that people must be given the opportunity to recognise this.<sup>158</sup> Implementation and dissemination of

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<sup>155</sup> Interview with SA\_26. His colleague, by contrast, thought that the three declarations as a suite were good documents and that there was still time for them to contribute to the "enabling legislative framework" that the National Biotechnology Strategy calls for, where there were still gaps in South Africa's legislation or regulations. (Department of Arts, Culture, Science and Technology, "A National Biotechnology Strategy for South Africa," 50.) The gaps he referred to, however, were in issues such as stem cell research, to which there are no references in the UNESCO declarations and, moreover, were to be covered in forthcoming national regulation; see 6.3.2.2. (Interview with SA\_31.)

<sup>156</sup> Interview with K\_19.

<sup>157</sup> Interviews with K\_03 and SA\_27. K\_03 made this comment in a personal capacity; SA\_27 said this was how most South African scientists felt towards getting involved in policy-making.

<sup>158</sup> Interview with SA\_11.

the declarations are discussed further in Chapter 6; Chapter 7 examines how networking around the declarations might be improved.

### 5.2.3 Implications for the GGI

Doubts about the expertise of the delegates who had represented their countries at international level and the lack of opportunities to feed into what negotiating positions those delegates should have taken resulted in some interviewees in Kenya and South Africa having little time for the UNESCO declarations. This would suggest that legitimacy springs as much from the manner in which an organisation makes its decisions as from whether or not these are made by states. Might the proposed GGI be more successful than UNESCO in selecting representatives and generating input from a wide variety of stakeholders, thus fostering legitimacy through strong leadership and inclusive membership as planned?

With regard to leadership, TJCB wrote in 2004 (as quoted previously in Chapter 2):

We are now in the process of bringing together some of the best creative minds from these fields [industry, academia, civil society, government] to begin the dialogue and to learn from their experiences so that any decision-making will come from the bottom up.<sup>159</sup>

As shown at 5.1.5.1, however, none of the participants in this study were among these “creative minds,” nor had several of them even heard of the proposed network, despite the fact that they represent a cross-section of southern expertise in different aspects of genetics and bioethics.<sup>160</sup> This would imply that the GGI, should it be established, might face the same legitimacy problems as UNESCO, its selection processes also lacking transparency. Some participants stressed that exactly who would be involved would be a vital factor in the GGI’s legitimacy. One welcomed the engagement with different sectors,

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<sup>159</sup> Acharya *et al*, “Better Global Governance to Promote Genomics for Development,” 6.

<sup>160</sup> Those from South Africa cannot have seen TJCB’s December 2005 invitation for comments and expressions of interest on the proposed GGI in the journal *Science and Public Policy*, which read, “Let the dialogue begin.” (Dowdeswell, Daar and Singer, “Getting Governance into Genomics,” 498.)



but nevertheless said that who was representing these would be significant.<sup>161</sup> Another saw the multisectoral approach as providing a “richness in input,” but only if the NGOs included were made up of “people from the ground.”<sup>162</sup>

In terms of wider input, TJCB intends that the proposed GGI would “exchange the politics of polarisation with a truly participatory process,” thereby facilitating global dialogue. Its aims include the provision of a discussion forum between the public and experts.<sup>163</sup> What form this would take is not articulated, although the internet-based Africa Genome Policy Forum (AGPF), convened after TJCB’s 2002 course on genomics policy (see 2.3.4.3), perhaps sets a precedent. Four of those in Kenya who had attended the course were interviewed. The first reported that no-one from the African Centre for Technology Studies, the course co-host, was still a member of the AGPF.<sup>164</sup> A second was no longer active on the forum because he did not have the time to be so. Both he and the third course participant said that contributions to the forum had slowed down greatly since its inception.<sup>165</sup> The fourth, on being asked about the AGPF, quipped, “Is that thing still alive?”<sup>166</sup> The failure of the AGPF does not bode well for TJCB’s plans for the GGI (or for Rischard’s ‘electronic town meetings’). One geneticist, pondering how the network might work in practice, asked, “Should it be internet based? Is that disempowering because only certain people can afford access to internet facilities?”<sup>167</sup> The realities of internet access in Africa are discussed further in the next chapter.

### 5.3 SUMMARY AND CONCLUSIONS

This chapter has shown that within UNESCO’s Bioethics Programme, relations between North and South and between state and non-state actors are ostensibly equal or at least

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<sup>161</sup> Interview with SA\_24.

<sup>162</sup> Interview with SA\_17.

<sup>163</sup> Dowdeswell *et al*, *op cit*, 132, 136, 138 and 139.

<sup>164</sup> Interview with K\_24.

<sup>165</sup> Interviews with K\_10 and K\_11 respectively.

<sup>166</sup> Interview with K\_12.

<sup>167</sup> Interview with K\_05.

balanced at international level. The organisation has put in place rules and procedures to ensure that voices from all states, along with experts and stakeholders in genetics and bioethics, have had the opportunity to be heard. Nevertheless, representation from developing countries has been disproportionately low at intergovernmental meetings and the ultimate power held by states has created something of a two-tier system of decision-making between them and non-state experts. At national level, in both Kenya and South Africa the legitimacy of the UNESCO declarations has been tarnished by people's perceptions that they were drafted in an unrepresentative and unaccountable manner. Although both countries had a presence at formal negotiations, if there was insufficient societal input into what their delegates were to take to the table, whether the people of Kenya and South Africa truly had a voice in these international deliberations is open to question. With regard to the proposed GGI, it would appear that few stakeholders in genetics and bioethics from the South (or at least from Kenya and South Africa) have been asked to join the network and that the plans for public participation may be beset by logistical hurdles, thus it may face similar legitimacy problems to UNESCO. How the problems of both organisations might be addressed is explored in Chapter 7. First, however, Chapter 6 examines the extent to which the UNESCO declarations are being implemented and enforced and whether the GGI would be likely to achieve its proposed goals, should it be established.



Chapter 5 examined issues of representation, legitimacy and accountability in the elaboration of UNESCO's declarations on genetics and bioethics and in the proposed Global Genomics Initiative. It showed that whether the declarations are perceived to have been negotiated in an expert, fair and democratic manner could have a profound effect on the likelihood of their being adopted. So too could the nature of the norms, rules and principles contained therein and the mechanisms put in place to promote them. This chapter examines the content and strength of the UNESCO norms and the organisation's efforts to ensure they will be realised. It analyses the extent to which member states, particularly Kenya and South Africa, are implementing the declarations within their laws, regulations and policies and in what specific areas they might need support and guidance. Whether the norms and aims of the proposed GGI might be complementary to these endeavours is also discussed.

## **6.1 NORMS**

Chapter 3 outlined two different categories of norms, namely those that govern decision-making procedures and those that prescribe rules and actions around particular issues. This section looks at the second kind, procedural norms having been examined in the previous chapter (in terms of which actors should be involved in deliberations and in what capacity). Specifically, it considers the prescriptive but non-binding norms on genetics and bioethics found within the three UNESCO declarations. It also ponders what the nature of the norms to be articulated by the GGI might be, should the network be established.

### 6.1.1 Norms in the UNESCO declarations

Although not explicitly articulated within the declarations themselves, UNESCO views the articles they promulgate as norms: “A declaration, although of a non-binding character, constitutes a standard-setting instrument in itself and therefore sets forth norms that States commit themselves to implement even if the term does not specifically figure in the text.”<sup>1</sup> The following sub-sections look at why UNESCO chose the declaratory and thus non-binding format for its instruments on genetics and bioethics, how states came to agree on the norms these instruments embody and what power, if any, lies behind the norms to ensure that states adhere to them. As shown at 2.3.4.1, the declarations elucidate norms on recognised bioethical principles such as autonomy and informed consent. They also contain several articles addressing issues pertinent to genetic and biomedical research in developing countries, including the transborder movement of samples and data; vulnerability; community engagement; the relevance of research to participants; benefit sharing; and genetics and ethics capacity building. (6.3.2 focuses on these issues, in the Kenyan and South African contexts.)

#### 6.1.1.1 Non-binding norms

For each UNESCO instrument, a decision had to be made as to what form it should take. The reasons given for the choice of a declaratory rather than conventional format were very similar in all three cases (and not uncommon among international institutions): firstly, states would be more likely to agree to non-binding norms; secondly, declarations are generally adopted more quickly than conventions; and thirdly, greater flexibility might be

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<sup>1</sup> UNESCO, “Information Meeting with IGBC on the Progress of the Elaboration of a Declaration on Universal Norms on Bioethics,” 4. The term ‘norm’ has been deliberately avoided in the case of the *Universal Declaration on Bioethics and Human Rights* (UDBHR, 2005), which was originally to be called *Declaration on Universal Norms on Bioethics*. The earlier title was seen to create confusion about the nature of the proposed document, stemming from the different types of norms recognised in international law: from the binding norms derived from treaties and conventions, to the non-binding norms of instruments such as declarations, to ‘programme norms’, which “are not lines of conduct but programmes of action.” (Ibid.)



beneficial in the rapidly changing fields of genetics and bioethics. For the UDHGHR (1997), the International Bioethics Committee (IBC) decided:

An instrument not requiring ratification, accession or acceptance, is likely to be adopted more quickly than a formal agreement, whereas the binding nature of a convention could well discourage certain States from committing themselves in so complex and changeable an area.<sup>2</sup>

For the IDHGD (2003), it was thought that a declaratory instrument would not only facilitate consensus during the negotiation period, but also “allow for adaptations in a domain where the variety of situations covered, and the complexity of the subject, is constantly evolving with new scientific discoveries.”<sup>3</sup> For the UDBHR (2005), the IBC again argued that a declaration would have the “greatest possible impact,” because it “would be better adapted to a constantly changing environment and would enable a broader consensus among Member States to be achieved rapidly.”<sup>4</sup>

The views of a Kenyan official at the Ministry of Foreign Affairs chime with this reasoning. He corroborated that states are more likely to agree to declarations than conventions. As Kenya would not be legally bound by a declaration, he said, it would not be too worried if not all its requirements were met during negotiations.<sup>5</sup> With regard to speed, the drafting process for each declaration was indeed relatively quick. The UDHGHR (1997) took only four years to finalise and the UDBHR (2005) less than two years.<sup>6</sup> The advantages of declarations over conventions in terms of adoption and speed carry a pay-off when it

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<sup>2</sup> UNESCO, *Birth of the Universal Declaration on the Human Genome and Human Rights*, 79.

<sup>3</sup> UNESCO, “UNESCO Adopts International Declaration on Human Genetic Data,” [http://portal.unesco.org/en/ev.php-URL\\_ID=16742&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=16742&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 21 June 2007).

<sup>4</sup> UNESCO, “Report of the Third Session of the IGBC,” 7-8.

<sup>5</sup> Interview with K\_30.

<sup>6</sup> UNESCO, *Birth of the Universal Declaration on the Human Genome and Human Rights*, 1; UNESCO, “Towards a Declaration on Universal Norms on Bioethics: Progress Report January 2005,” PowerPoint presentation available at [http://portal.unesco.org/shs/en/file\\_download.php/50523d754289e00aad6d16990d576e22Bioethics+Declaration\(jan.2005\).ppt](http://portal.unesco.org/shs/en/file_download.php/50523d754289e00aad6d16990d576e22Bioethics+Declaration(jan.2005).ppt) (accessed 9 July 2007). The speed with which the UDBHR was drafted was at the expense of a better document, in the opinion of one attendee at the IGE meetings. (Interview with UK\_02.) Similarly, the two years the Bioethics Programme was given to elaborate the declaration had been “completely unrealistic,” according to a member of the secretariat, although it had responded by making the process much more intensive than for the previous declarations. (Interview with F\_01.) A sense of urgency did not permeate the January 2005 IGBC and IBC meetings, however. They did not start on time and coffee and lunch breaks lasted longer than stipulated in the programme. During negotiations the IGBC chair made several pleas for brevity, describing the quick and efficient discussion of one section of the declaration as a “demi-miracle.” (IGBC and IBC meetings, Paris, 24 to 28 January 2005, personal observations.)

comes to the persuasive force of their norms and the rate at which they are implemented, however (see 6.1.1.3). The argument for declaratory instruments on the grounds of flexibility is less defensible, as illustrated below.

#### **6.1.1.2 Norm content**

Apart from the reasons outlined above, declaratory instruments were also considered appropriate because states would be able to interpret them as they saw fit within their national contexts. As identified in Chapter 2, UNESCO's aim has been to elaborate universal norms that take account of the different traditions of its member states.

Accordingly, the UDHGHR (1997) is intended to "transcend different cultural, political and religious sensitivities,"<sup>7</sup> whilst for the IDHGD (2003), "the declaratory form of the instrument was chosen for its appropriateness in the elaboration of principles that States can interpret taking into account their legal systems and different cultural, economic and social circumstances."<sup>8</sup> The General Conference commissioned a balanced approach to the drafting of the UDBHR (2005), judging that universal standards were needed in bioethics, but that these should be set "in the spirit of cultural pluralism *inherent in bioethics*"<sup>9</sup> (*italics added*).

In order that these mandates be fulfilled, the declarations contain only general principles, to which all states were able to agree without conceding their cultural and political particularities.<sup>10</sup> Thus they are more in keeping with Young's observations about the messy process of regime negotiation than with Victor *et al*'s on non-binding agreements

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<sup>7</sup> UNESCO, *Birth of the Universal Declaration on the Human Genome and Human Rights*, 28. During the drafting of the declaration Alastair Iles averred that it would be "constrained in its vision and transformative potential," because of the need to accommodate "vast cultural and political diversity." (Iles, "The Human Genome Project," 43.)

<sup>8</sup> UNESCO, "Meeting of Government Experts Responsible for Finalizing the Draft International Declaration on Human Genetic Data: Final Report," 3.

<sup>9</sup> Resolution 24. UNESCO, "Volume 1: Resolutions," Records of the General Conference, 32nd Session, Paris, 29 September to 17 October 2003, 32 C/Resolutions (Paris: 2004), 47.

<sup>10</sup> Roberto Andorno, a member of the IBC during the drafting of the UDBHR, writes of the declaration, "Regardless of the weaknesses inherent to this kind of instrument, the very fact that virtually all states reached an agreement in this sensitive area is in itself a major achievement." (Andorno, "Global Bioethics at UNESCO," 150.)



encapsulating less compromised standards than binding ones (see 3.5.3). Articles are more or less specific depending on the issue concerned. Some appear reasonably detailed. All three declarations, for example, lay out guidelines for authorisation for research with persons without the capacity to consent<sup>11</sup> and the IDHGD (2003) and UDBHR (2005) offer concrete suggestions as to what benefit sharing might actually entail, such as provision of new diagnostics and drugs or capacity building in data collection and research.<sup>12</sup> Even so, these are minimal in comparison with the equivalent sections of the CIOMS (Council for International Organizations of Medical Sciences) *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002), which run to several paragraphs.<sup>13</sup>

Other articles in the declarations use vague or non-committal language and some controversial issues were avoided altogether.<sup>14</sup> A significant feature of the UDHGHR (1997) is that it says of the human genome, "In a symbolic sense, it is the heritage of humanity" (article 1). Although UNESCO considered this conceptually innovative, the stronger formulation "common heritage of humanity" was used in earlier drafts, a recognised term in international law (as applied to the sea and outer space, for example) and the one adopted by the Human Genome Organisation. Noëlle Lenoir, then president of the IBC, described the application of this legal term to the human species as "the main originality" of the draft declaration.<sup>15</sup> Member states made the change, concerned that the

<sup>11</sup> UDHGHR, article 5e; IDHGD, articles 8b and c; UDBHR, article 7. The stipulations of the declaration on human genetic data (IDHGD, 2003) are less detailed than those of the other two declarations in this regard, perhaps because of the potentially smaller risk associated with the collection of genetic samples or information than with other forms of biomedical research.

<sup>12</sup> IDHGD, article 19; UDBHR, article 15.

<sup>13</sup> CIOMS, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, guidelines 9 and 15 (research with those without the capacity to consent) and 7, 10 and 21 (benefit sharing). Ruth Macklin sees the UDBHR (2005) as striking the right balance between brevity and "a rehearsal of mere pieties." She acknowledges that it is not as detailed as the CIOMS guidelines, but compares it favourably with the *Declaration of Helsinki* in terms of ground covered. (Macklin, "Yet Another Guideline?" 248.)

<sup>14</sup> Several commentators have criticised the declarations for being vague and indeterminate. (Harmon, "The Significance of UNESCO's Universal Declaration on the Human Genome & Human Rights," 33; Taylor, "Globalization and Biotechnology," 510; Abbing, "International Declaration on Human Genetic Data", 93; Landman and Schüklenk, "From the Editors," iv; Williams, "UNESCO's Proposed Declaration – A Bland Compromise," 213; Benatar, "The Trouble with Universal Declarations," 221.) Some IBC members have framed the declarations' generality more positively, as a necessary step in reaching an international consensus from which states can draw in making more firm regulations. (Andorno, "Biomedicine and International Human Rights Law," 960; Butler (verbally quoting Lenoir), "Ethics Treaty to Target Genome Implications," 369.)

<sup>15</sup> Lenoir, "Bioethics and UNESCO," 12-22.



idea of “common heritage” could be misconstrued to justify the appropriation of human genetic sequences for commercial purposes.<sup>16</sup> Relatedly, they added an article on commercialisation just before the declaration was adopted: “The human genome in its natural state shall not give rise to financial gains” (article 4).<sup>17</sup> While this would appear to guard against gene patenting, the phrase “in its natural state” renders the article ambiguous. “Given that the ethical and legal problem is raised precisely by the patenting of human DNA sequences in something other than its natural form,” writes Roberto Andorno, “...the Declaration gives the impression of having eluded the real problem.”<sup>18</sup> Eike-Henner Kluge makes a similar criticism, arguing that the article could be interpreted to justify gene patenting on the grounds that this concerns only parts of the human genome, which if separated from “their contextual DNA” would not be in their natural state.<sup>19</sup> (Issues around patenting, with their ensuing implications for benefit sharing, also arose during the negotiations for the IDHGD (2003), resulting in the compromises described at 5.1.1.2.)

There were a number of issues during the drafting of the UDBHR (2005) that proved difficult or impossible to resolve. Group IV (Asian) and Group I (Western European and other) states were at odds over whether the declaration should extend to the biosphere or be limited to humans<sup>20</sup> and a definition of the term ‘bioethics’ had to be dropped because consensus on wording and scope could not be reached.<sup>21</sup> Of most relevance to research ethics was the furore over an article on risk assessment; states were unable to agree whether or not it should incorporate the precautionary principle.<sup>22</sup> The eventual resolution at the June IGE session epitomises many regime negotiations: “The meeting decided to

<sup>16</sup> Andorno, “Seeking Common Ground on Genetic Issues,” 107.

<sup>17</sup> Knoppers, “Status, Sale and Patenting of Human Genetic Material,” 24.

<sup>18</sup> Andorno, “Seeking Common Ground on Genetic Issues,” 111.

<sup>19</sup> Kluge, “Patenting Human Genes,” 124.

<sup>20</sup> The debate concerning the scope of the declaration, in terms of how far it should address the biosphere and environmental issues, pervades the copious UNESCO documentation concerning the UDBHR cited in this thesis.

<sup>21</sup> UNESCO, “Second Session of the Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics: Final Report,” 2-3.

<sup>22</sup> The precautionary principle can be defined as follows: “Precaution—the ‘precautionary principle’ or ‘precautionary approach’—is a response to uncertainty, in the face of risks to health or the environment. In general, it involves acting to avoid serious or irreversible potential harm, despite lack of scientific certainty as to the likelihood, magnitude, or causation of that harm.” (The Precautionary Principle Project, “What Is the Precautionary Principle?” [www.pprinciple.net/the\\_precautionary\\_principle.html](http://www.pprinciple.net/the_precautionary_principle.html), accessed 2 November 2007.)



retain the article by amending it in such a way as to formulate a general principle without going into detail.”<sup>23</sup> Hence the article’s rather nebulous wording:

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted<sup>24</sup>

as compared with draft formulations, for example:

When scientific evidence of serious or irreversible damage to public health or human welfare or the environment is not sufficient, provisional, adequate and proportionate measures shall be taken in a timely manner. Such measures shall be based on the best scientific knowledge available and on procedures that are specially designed for evaluating the ethical issues at stake. These measures should be carried out in accordance with the principles set out in this Declaration and with respect to human rights and fundamental freedoms.<sup>25</sup>

It seems, then, that the ‘lowest common denominator’ effect could not be avoided in this case, despite the non-binding nature of the declaration.

How controversial issues in bioethics might be included in the text also proved irresolvable. Thus no mention is made of gene therapy or stem cell research, for instance. Instead, general and procedural principles are intended to provide a basis for “the search for common positions” on issues for which no such position could be found in specific terms.<sup>26</sup> The IBC tried to make provision for these issues to figure in future revisions to the declaration, with the following clauses:

31 (c) Five years after its adoption and thereafter on a periodical basis, UNESCO shall take appropriate measures to examine the Declaration in the light of scientific and technological development and, if necessary, to ensure its revision, in accordance with UNESCO’s statutory procedures

and

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<sup>23</sup> UNESCO, “Second Intergovernmental Meeting of Experts: Final Report,” 7.

<sup>24</sup> UDBHR, article 20.

<sup>25</sup> UNESCO, “Elaboration of the Declaration on Universal Norms on Bioethics: Fourth Outline of a Text,” SHS/EST/04/CIB-Gred-2/4 Rev. 3 (Paris: 15 December 2004), 8 (article 23).

<sup>26</sup> UNESCO, “Second Meeting of the IBC Drafting Group for the Elaboration of a Declaration on Universal Norms on Bioethics,” 1.

31 (d) With respect to the principles set forth herein, this Declaration could be further developed through international instruments adopted by the General Conference of UNESCO, in accordance with UNESCO's statutory procedures.<sup>27</sup>

The governmental representatives removed the clauses at their June 2005 IGE meeting, however, considering them inappropriate.<sup>28</sup> Thus it appears that the declaration will be less flexible in a “constantly changing environment” than the IBC initially hoped.

#### **6.1.1.3 The strength of non-binding norms**

Although the declarations, by definition, cannot be binding, what states might seemingly be obligated to do was still of concern during negotiations. There was substantial debate during the drafting of both the IDHGD (2003) and the UDBHR (2005) over whether states ‘shall’ or ‘should’ implement their principles. At the IDHGD IGE meeting, “the participants agreed that insofar as possible the word ‘shall’ would be replaced by ‘should’ or by ‘may’ in the text of the preliminary draft.”<sup>29</sup> For the UDBHR, some states felt that ‘shall’ could be used as an indication of moral commitment, without compromising the non-binding nature of the text, whilst others were adamant that only the conditional form was appropriate within a declaration (except in regard to actions prescribed for UNESCO).<sup>30</sup> A more specific example concerns the free flow and sharing of scientific and technological knowledge. An article in the draft UDBHR asserting that states should “make every effort to guarantee” these was softened so that they should merely “encourage” them, after several members of the Intergovernmental Bioethics Committee (IGBC) objected to the

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<sup>27</sup> UNESCO, “Elaboration of the Declaration on Universal Norms on Bioethics: Fourth Outline,” 10. The Director-General of UNESCO and Justice Kirby, chair of the UDBHR’s drafting group, both remarked at the January 2005 IGBC and IBC meetings that consensus on the more controversial issues might be possible in the future and therefore the draft declaration made provision for this. (IGBC and IBC meetings, Paris, 24 to 28 January 2005, personal observations.)

<sup>28</sup> UNESCO, “Second Intergovernmental Meeting of Experts: Final Report,” 7-8.

<sup>29</sup> Only in relation to the IBC and IGBC was ‘shall’ retained. (UNESCO, “Meeting of Government Experts: Final Report,” 4.)

<sup>30</sup> Interview with UK\_01; UNESCO, “First Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics: Final Report,” 3. Some states were giving their positions on this issue from the second written consultation onwards (October to December 2004). (UNESCO, “Results of the Written Consultation on the Third Outline of the Text of a Declaration on Universal Norms on Bioethics (27 August 2004),” 1, 3, 7, 19, 21, 24, 26, 32 and 33.)



stronger formulation at the January 2005 meetings.<sup>31</sup> (See also 6.2.3, which considers states' objections to reporting requirements.)

Members of the Bioethics Programme's secretariat place a high value on the commitment of states to the implementation of the declarations that each of the texts articulates. Jan Helge Solbakk, chief of the Bioethics Section, in a presentation on the UDBHR, opined that this commitment made the declaration "harder than soft law," in that it differed from a document like the World Medical Association's *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, which can have only moral weight.<sup>32</sup> Another member of the Programme said in an interview that if the declarations were taken up by states in national legislation, they would override all other existing international instruments (although he thought this adoption rather unlikely to happen).<sup>33</sup>

The three declarations vary slightly in what is expected of member states in terms of compliance. While several articles of the UDHGHR (1997) allude to national law in relation to research ethics, confidentiality and reparation for damage,<sup>34</sup> the section on promotion of its principles requires states to do this "through education and relevant means" and "all appropriate measures" (whatever those might be), rather than through codification *per se*.<sup>35</sup> In the IDHGD (2003) and the UDBHR (2005) the legislative push is stronger: states are to "take all appropriate measures, whether of a legislative, administrative or other character," to give effect to the declarations' principles.<sup>36</sup> This stipulation is reinforced in the UDBHR, one of its stated aims being to provide a universal framework to guide states in formulating legislation, policies or other instruments on bioethics.<sup>37</sup> Two South African geneticists said the declarations would need action behind them to move them beyond

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<sup>31</sup> UNESCO, "Elaboration of the Declaration on Universal Norms on Bioethics: Fourth Outline," 9 (article 28 (a)); UDBHR, article 24 (1). The states which objected were Canada, Germany, Saudi Arabia, Latvia and the United States (IGBC meeting, Paris, 25 January 2005, personal observations.)

<sup>32</sup> Jan Helge Solbakk, "Towards a Global BioPolicy? The UNESCO Universal Declaration on Bioethics and Human Rights in Perspective," keynote speech, BioCentre: Global Perspectives on BioPolicy Symposium Series, London, 16 March 2007. Macklin echoes this, seeing the UDBHR's "greatest strength" in its "stature as an international declaration issued by a United Nations Organization." (Macklin, *op cit*, 244.)

<sup>33</sup> Interview with F\_01.

<sup>34</sup> UDHGHR, articles 5, 7 and 8.

<sup>35</sup> *Ibid*, articles 20 and 22.

<sup>36</sup> IDHGD, article 23; UDBHR, article 22.

<sup>37</sup> UDBHR, article 2 (a).

being merely “a nice statement” or “nice platitudes.”<sup>38</sup> One supporter of the declarations agreed: “I think that this [the UDBHR] has been a helpful document and now it’s just a matter of how it filters down to more of a grassroots level.”<sup>39</sup> (6.3 onwards looks at how far this is in fact happening.)

In several of its reports concerning the declarations, UNESCO refers to the practice within the UN of first adopting a declaration and then following up with a binding instrument at a later date (as was the case with the *Universal Declaration of Human Rights* and the subsequent covenants on political, social and economic rights). Federico Mayor, former Director-General of UNESCO, wrote in the preface to a book on the history of the UDHR (1997), “Eventually, UNESCO should perhaps, on the basis of a searching evaluation of the measures taken and the prevailing situation, take the initiative once again so as to entrench the principles enshrined in the Declaration more firmly in law.”<sup>40</sup> In reality, the evaluation UNESCO undertook proved less than searching (see 6.2.3).

Mayor’s use of the word ‘eventually’ and the fact that, ten years after the declaration was adopted, there is no hint that a convention might be forthcoming are perhaps indicative of the time delays that can occur within traditional IGOs, as identified by Rischard.<sup>41</sup> A member of the Bioethics Programme thought it might be possible to combine the 1997 and 2003 genetics declarations to form a convention in the future, but said that this would depend on the global political climate; for conventions, he observed, “the politics is much heavier.”<sup>42</sup>

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<sup>38</sup> Interviews with SA\_27 and SA\_20 respectively.

<sup>39</sup> Interview with SA\_37.

<sup>40</sup> UNESCO, *Birth of the Universal Declaration on the Human Genome and Human Rights*, III.

<sup>41</sup> After three declarations, UNESCO is taking a “normative pause” and instead concentrating on supporting the implementation of the declarations at regional and national levels. (UNESCO, “Address by Mr Koïchiro Matsuura, Director General of UNESCO,” twelfth session of the IBC, Tokyo, Japan, 15-17 December 2005, DG/2005/201, 4.)

<sup>42</sup> Interview with F\_01.



### 6.1.2 Duplication of norms

As articulated in Chapters 2 and 5, the declarations are considered by UNESCO to be unique among international bioethics instruments because they have been agreed by states. At the June 2005 IGE meeting, the Director-General declared that the UDBHR, once adopted, would “close a wide gap at the international level.”<sup>43</sup> The declarations’ intergovernmental origins were not necessarily seen as significant by those in Kenya and South Africa who practise bioethics, however, many of whom refer to the *Declaration of Helsinki* and the CIOMS guidelines for international level guidance and thus do not perceive there to have been the same “wide gap” as did the Director-General.<sup>44</sup> Particularly with regard to the UDBHR (2005), several people saw what to them was simply another international bioethics declaration as unnecessary, or thought that people might become confused as to which guidelines (and the norms contained therein) to follow. One lamented, “There is a plethora of different guidelines that people are trying hard to get to grips with.” Another, who sits on several research ethics committees (RECs), was of the opinion that there are too many “talk-shops” coming up with declarations, to the detriment of implementation “on the ground.”<sup>45</sup>

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<sup>43</sup> UNESCO, “Second Intergovernmental Meeting of Experts: Final Report,” Annex II, 1-2.

<sup>44</sup> Professor Henk ten Have of the Bioethics Programme has described the governmental commitment as the “innovative dimension” of the bioethics declaration (ten Have, “The Activities of UNESCO in the Area of Ethics,” 342.) The declaration is also considered to go further than existing codes of ethics, because it is not confined to research ethics. (UNESCO, “Report by the Director-General on the Drawing Up of a Declaration on Universal Norms for Bioethics,” 6.) Since this thesis is concerned with research ethics only, however, to what degree the declarations go beyond existing codes in this area in particular is of primary interest. The Helsinki declaration and the CIOMS guidelines have been adopted by professional organisations rather than UN agencies (although CIOMS is in official relations with WHO). Where the former is officially directed at physicians or researchers, however, the latter, like the UNESCO declarations, are intended to be used in the designing of national policy on biomedical research ethics, particularly in developing countries (World Medical Association, *Declaration of Helsinki*, 1; CIOMS, op cit.) The Helsinki declaration is generally considered the foremost document globally on medical research ethics and, with the CIOMS guidelines, forms the bedrock of research ethics in many developing countries. (Carlson, Boyd and Webb, “The Revision of the Declaration of Helsinki,” 695; Fluss, “The Evolution of Research Ethics,” 601; Bhutta, “Ethics in International Health Research,” 115.) The UDBHR is unusual among international instruments in that it notes these non-UN documents in its preamble. This is because, during the drafting, bioethicists found it strange that these should be excluded from the text. (Comment by Justice Kirby, IGBC meeting, Paris, 25 January 2005, personal observation.) A member of the UNESCO Bioethics Programme, in an interview in August 2005, acknowledged that the Helsinki declaration was better known among scientists and researchers than the UNESCO declarations. (Interview with F\_01.) The following scientists and ethics committee members said that their institutions refer to the Helsinki declaration and the CIOMS guidelines: K\_06, K\_07, K\_08, K\_09, K\_17, K\_19, SA\_10, SA\_04, SA\_14, SA\_19, SA\_24, SA\_30 and SA\_35.

<sup>45</sup> Interviews with K\_06 and SA\_17 respectively (both quoted). K\_07, K\_09, K\_17, K\_28, SA\_04, SA\_08, SA\_10, SA\_14, SA\_15, SA\_20, SA\_25, SA\_27, SA\_33 and SA\_35 made similar comments. One person opined that although the declarations are useful as a reference point, by and large research ethics committees in South Africa are already aware of the principles enshrined in the declarations’ articles. (Interview with SA\_32.)



Other participants were more positive about the declarations. Some thought them complementary to pre-existing instruments or that it was useful to be able to draw on different perspectives.<sup>46</sup> As an illustration, researchers at the Kilifi KEMRI-Wellcome Trust Collaborative Programme in Kenya and the South African National Bioinformatics Institute, when faced with a particular ethical problem, will look to synthesise all the relevant resources in order to reach the most appropriate solution.<sup>47</sup> Some interviewees valued the declarations as benchmarks that could be referred to in lobbying for the introduction of internationally agreed standards at national level,<sup>48</sup> or like UNESCO saw additional guidelines as necessary in an era of new technologies and scientific developments.<sup>49</sup> A member of two Kenyan RECs, for example, was particularly interested in the genetics declarations, because she thought it likely her committees would have to assess a growing number of protocols for research in this area in the future.<sup>50</sup> Several welcomed all three declarations as reinforcing and fleshing out important principles of social responsibility, benefit sharing and capacity building.<sup>51</sup>

The GGI, should it be established, would, like UNESCO, elaborate norms on genetics and bioethics. TJCB's most recent publication (2006) on the proposed network includes among the projected aims, "The GGI could also help draft norms and principles for the global harmonisation of ethical standards applied to genomic technology research, with benefit sharing and risk minimisation."<sup>52</sup> "Global harmonisation" implies that these norms would be definitive, yet it seems unlikely that they would be accepted as such unless the GGI should develop a profile to rival that of the UN, or indeed the World Medical Association or CIOMS. Also implied in this aim is that the GGI would fill a gap in currently

<sup>46</sup> Interviews with SA\_06, SA\_24, SA\_25, SA\_26, SA\_30, SA\_31.

<sup>47</sup> Interviews with K\_07 and SA\_02.

<sup>48</sup> K\_16 (informal conversation), SA\_13, SA\_23 and SA\_30. Henriette Abbing, writing soon after the adoption of the UDHGHR (1997), saw it as having this potential: "The Declaration, in providing a framework which is based on general consensus, certainly will support developments in those countries where human rights in relation to genetics are not yet sufficiently guaranteed by the law nor applied in practice. It can be called upon in case of practices not in line with the principles layed [sic] down in the declaration." (Abbing, "New Developments in International Health Law," 157.) David Benatar has similarly said of the UDBHR, "In favour of declarations it might be said that they constitute a rallying cry, an effective political instrument for noble ideas." (Benatar, *op cit*, 223.)

<sup>49</sup> K\_10, K\_19, K\_29 and SA\_32.

<sup>50</sup> Interview with K\_25.

<sup>51</sup> Interviews with K\_17, K\_19, SA\_12, SA\_24, SA\_33 and SA\_37.

<sup>52</sup> Dowdeswell *et al*, "Realising the Promise of Genomics," 138.



existing norms in genetics and bioethics (as espoused by the various bodies already mentioned, including UNESCO), by encouraging risk minimisation. What direction this might take is perhaps indicated by TJCB's deeming the GGI necessary partly because "traditional governance models" focus disproportionately on risk and restriction.<sup>53</sup> The UNESCO declarations cannot be charged with any such failing, however; alongside ethical procedures, they advocate scientific freedom, capacity building and the promotion of science and technology for addressing inequalities of health.

## **6.2 INTERNATIONAL IMPLEMENTATION AND ENFORCEMENT**

The real key to whether UNESCO's declarations or the proposed GGI's norms and principles can be successful as instruments of governance will lie in the extent to which they are taken up by states and other actors; having formalised norms is only a first step. This is illustrated by quotes from two participants. The first said of UNESCO, "Of course, the implementation is quite different from the declarations themselves," whilst the second said of the GGI, "Of course, there's one thing with coming up with guidelines and [another] people adhering to them."<sup>54</sup> The UNESCO Director-General has similarly commented on the UDBHR (2005), "Its adoption is just the beginning. To give full life to the Declaration and render it effective, the most important part of the work remains to be done."<sup>55</sup> Whilst a non-binding instrument will have been more likely than a binding one to foster broad agreement during negotiations on what its various principles should be, acceptance at national level in terms of implementation will be less certain, precisely because it cannot be enforced. This section examines UNESCO's attempts to ensure its member states take up the genetics and bioethics declarations and assesses whether the GGI's planned activities would be likely to be carried out successfully. Although the declarations might be considered "harder than soft law," it will be shown that implementation activities on the

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<sup>53</sup> Ibid, 134.

<sup>54</sup> Interviews with K\_29 and SA\_19 respectively.

<sup>55</sup> UNESCO, "Address by Mr Koïchiro Matsuura, Director-General of UNESCO," twelfth session of the IBC, 3.

part of UNESCO tend to take a management approach, aimed at encouragement and facilitation. This is particularly the case with regard to what the declarations seemingly obligate states to do, their non-binding status notwithstanding, such as reporting to UNESCO on a regular basis (see 6.2.3). The GGI, should it be established, may have to employ similarly gentle tactics.

### 6.2.1 Capacity building

One of UNESCO's foremost activities in promoting the declarations is dissemination, in order that they reach as wide an audience as possible. By October 2001, half a million copies of the UDHGHR (1997) had been published, in twenty languages. Furthermore, over eighty articles on the declaration had been published worldwide and over forty television and radio interviews given. The International Society of Bioethics awarded its 2002 Prize to UNESCO, for its work on the UDHGHR and in bioethics in general.<sup>56</sup> Nevertheless, as shown in Chapter 5, the declaration does not appear to be widely known, at least in Kenya and South Africa. This is also the case for the second declaration, the IDHGD (2003). Almost two years after its adoption, many countries were "not even aware that there is such a declaration."<sup>57</sup> One interviewee, a geneticist, suggested that UNESCO publish the declarations in scientific journals, to heighten awareness among his community.<sup>58</sup>

UNESCO also disseminates reports by the IBC that give guidance on particular principles of the declarations or on contemporary issues in bioethics. A member of the Bioethics Programme explained that, because member states sometimes arrive at a formulation for an article that is "open to multiple interpretations," one of the IBC's duties is to work out how to go from "the very general level of the principle to much more practical guidelines,

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<sup>56</sup> UNESCO, "Bioethics Programme: Priorities and Prospects," 162 EX/13, 6 and 7.

<sup>57</sup> Portugal, Israel and Turkey are exceptions, where IBC members have liaised with their National Commissions to provide local translations. (Interview with F\_01.)

<sup>58</sup> Interview with K\_05.



how to do it in different countries and cultures.”<sup>59</sup> Such reports were welcomed by a university lecturer and member of several ethics committees, as she surmised that the declarations themselves were probably “very distilled, easily misinterpreted perhaps, truncations.” She was unenthused by the IBC’s reports on cutting edge technologies, however, which she described as “totally irrelevant to the vast majority of the world.”<sup>60</sup> A South African geneticist echoed these sentiments.<sup>61</sup> The most recent reports examine how some of the standards set in the UDBHR (2005) on informed consent and social responsibility might be implemented. Draft versions were presented at the fourteenth session of the IBC in Nairobi, Kenya, in May 2007.<sup>62</sup> The report on informed consent (finalised in Kenya) provides explanations of the relevant principles in the UDBHR and gives examples of how they might be applied in certain contexts, while the draft report on social responsibility outlines issues and initiatives around global health.<sup>63</sup> In the biennium 2008-2009 the IBC is to continue to work on social responsibility and health and to begin to explore issues around article 8 of the UDBHR, on human vulnerability and personal integrity. It may also look at neuroethics, genetic testing and traditional medicine and biopiracy.<sup>64</sup> Much of the IBC’s current work, then, concerns matters that might be considered to be of particular interest to developing countries. All the committees’ reports, as well as other documentation about UNESCO’s ethics programmes, are freely available on the UNESCO website.<sup>65</sup>

A third information source provided by UNESCO is the Global Ethics Observatory (GEObs), launched in December 2005.<sup>66</sup> GEObs covers the ethics of science and technology and the environment as well as bioethics and hosts five web-based databases, comprising ethics experts, institutions (including national bioethics committees), teaching

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<sup>59</sup> Interview with F\_01.

<sup>60</sup> Interview with SA\_14.

<sup>61</sup> Interview with SA\_20.

<sup>62</sup> UNESCO, “Fourteenth Session of the International Bioethics Committee, Nairobi, Kenya, 17-19 May 2007: Programme,” SHS/EST/CIB-14/07/CONF.507/INF.2 (4 May 2007).

<sup>63</sup> UNESCO, “Report of the IBC on Consent” and “Preliminary Draft Report of the IBC Working Group on Social Responsibility and Health.”

<sup>64</sup> UNESCO, “Work Programme of IBC for 2008-2009,” SHS/CIB-14/07/CONF.507/INF.6 (Paris: 1 June 2007).

<sup>65</sup> See [www.unesco.org/bioethics](http://www.unesco.org/bioethics).

<sup>66</sup> GEObs can be accessed at [www.unesco.org/shs/ethics/geobs](http://www.unesco.org/shs/ethics/geobs). It is available in all six official languages of UNESCO: Arabic, Chinese, English, French, Russian and Spanish.

programmes, legislation or guidelines and codes of conduct.<sup>67</sup> UNESCO believes that GEObs will be a “crucial platform” for supporting member states in their ethics activities.<sup>68</sup> People designing new ethics courses might use the education section to seek the advice of those with previous experience, for example: “It’s a kind of facilitator of contacts among different people.”<sup>69</sup> Thus GEObs has the potential to become a Slaughter-like information network (see 7.6).

Several South African interviewees welcomed the GEObs initiative, partly because it would provide information they did not have access to elsewhere.<sup>70</sup> One ethics lecturer asserted, “It would be very useful, absolutely. I certainly don’t know of anything like that.”<sup>71</sup> A second thought the education section would help people enrolling in ethics programmes to ensure that they were going to be taught by suitably qualified teachers rather than “fly-by-night” ethicists (who “waltz in and start teaching ethics without proper training”) and might also highlight where courses are lacking and thus encourage more funding (this is indeed a secondary purpose of the initiative, see 6.2.3).<sup>72</sup> One person who had been asked to provide information concerning his institution’s interest in the GEObs programme was less enthusiastic, however, as this would require devoting considerable time to what seemed like a focus on the “bureaucratic organisation” of research ethics, rather than scholarly aspects of bioethics, which require more attention.<sup>73</sup>

UNESCO’s website headlines, “UNESCO’s new Global Ethics Observatory puts ethics within everyone’s reach.”<sup>74</sup> In particular, it is hoped that GEObs will enable people in developing countries to access resources such as reports and guidelines quickly.<sup>75</sup> As per the consultation on the draft bioethics declaration (see Chapter 5, note 77), there appears

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<sup>67</sup> UNESCO, “GEObs: Global Ethics Observatory,” SHS-2006/WS/9/REV (Paris: 2006).

<sup>68</sup> UNESCO, “Global Ethics Observatory (GEObs),” [www.unesco.org/shs/ethics/geobs](http://www.unesco.org/shs/ethics/geobs) (accessed 22 August 2007).

<sup>69</sup> Interview with F\_01.

<sup>70</sup> Interviews with SA\_08, SA\_10, SA\_15, SA\_24, SA\_35 and SA\_37.

<sup>71</sup> Interview with SA\_14.

<sup>72</sup> Interview with SA\_16.

<sup>73</sup> Interview with SA\_09.

<sup>74</sup> UNESCO, “UNESCO’s new Global Ethics Observatory puts Ethics Within Everyone’s Reach,” [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=9084&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=9084&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 22 June 2007).

<sup>75</sup> Interview with F\_01.



to be an assumption that the internet is easily or freely available to all. This is not necessarily the case, however, especially in the South. The IBC's own draft report on social responsibility and health notes that 80 per cent of the world's population does not have access to basic telecommunications technology.<sup>76</sup> One African delegate to the January 2005 joint IGBC and IBC sessions described how it had been difficult for him to access the relevant documents before the meetings because his office did not have an internet connection, which had a detrimental effect on his preparations.<sup>77</sup> Similarly, a Kenyan representative at the April and June IGE meetings explained that his internet access was slow and costly. He surmised, "So many people are not even interested to know—if you are not directly involved, why should you read about UNESCO?"<sup>78</sup> These testimonies bear out Chasek and Rajamani's observations concerning the accessibility of online documentation to IGO delegates from developing countries. Others in Kenya, also connected with UNESCO, viewed new communications technologies more positively, however, believing they could facilitate the country's greater involvement in bioethics and genetics. A member of the National Commission believed email would enable Kenya to assert itself more strongly on the IGBC, whilst in regard to capacity development in science and technology, a scientific advisor to the Commission and the Kenyan government averred, "We don't need to build new buildings, we can communicate through the internet."<sup>79</sup>

Alongside information dissemination, UNESCO has more active programmes aimed at facilitating uptake of the declarations. Firstly, under the auspices of the Bioethics Programme, it supports the establishment of national bioethics committees. These committees provide a clear point of contact with which the Programme can liaise and are seen as intermediary steps towards the long-term goal of state level legislation.<sup>80</sup> According to a report from 2001, committees had then been set up in seven countries, including South Africa (although this was not mentioned by a single participant during

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<sup>76</sup> UNESCO, "Preliminary Draft Report of the IBC Working Group on Social Responsibility and Health," 8.

<sup>77</sup> IGBC and IBC meetings, Paris, 24 to 28 January 2005, informal conversation.

<sup>78</sup> Interview with K\_01.

<sup>79</sup> Interviews with K\_16 and K\_13 (quoted) respectively.

<sup>80</sup> Interview with F\_01.

fieldwork).<sup>81</sup> More recently, this work has continued under a programme entitled Assisting Bioethics Committees. In 2007, for example, committees were to be established in Ghana and Togo.<sup>82</sup> As well as this direct support, the programme distributes guidelines on how to set up, run and educate bioethics committees, with a further volume on public outreach forthcoming.<sup>83</sup> Some interviewees welcomed these.<sup>84</sup> One, who teaches on the southern African research ethics training programme SARETI (see 6.3.2.3), described the guidelines as “very, very useful,” as for many students their first task on returning to their home countries is to form an ethics committee.<sup>85</sup> As with the declarations themselves, however, some people were ambivalent, because they did not see “a big gap in literature.”<sup>86</sup>

UNESCO's second capacity building activity is the Ethics Education Programme (EEP), which is developing a pilot programme on how to teach ethics in science and technology and a core course on bioethics, based on the principles of the UDBHR.<sup>87</sup> Beyond facilitating the fulfilment of the particular articles in the three declarations concerning ethics education and training,<sup>88</sup> UNESCO hopes that the EEP (with the education section of GEObs) will ensure that “future generations of scientists and professionals” learn the principles in the declarations, whether or not states develop legislation.<sup>89</sup> In 2004-2005 the EEP focused on East and Central Europe. In 2006-2007 it was to have concentrated on African, Arab and Asian countries, according to the EEP webpage in 2005, but a

<sup>81</sup> UNESCO, “Bioethics Programme,” 162 EX/13, 6. The other countries were Algeria, Côte d'Ivoire, Jamaica, Morocco, Nepal and Senegal.

<sup>82</sup> UNESCO, “The UNESCO Bioethics Programme: Promotion and Dissemination of the Universal Declaration on Bioethics and Human Rights and Capacity-building Activities,” presentation at the fourteenth session of the IBC, Nairobi, Kenya, 17 to 19 May 2007.

<sup>83</sup> ten Have, op cit, 346; UNESCO, “Guide No. 3: Educating Bioethics Committees,” [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=11327&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=11327&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 18 September 2007).

<sup>84</sup> Interviews with SA\_10 and SA\_15.

<sup>85</sup> Interview with SA\_24.

<sup>86</sup> Interviews with SA\_37 (quoted), K\_21, SA\_17 and SA\_35. Some of these interviewees were concerned that UNESCO's guidelines would duplicate national and international documents that deal specifically with research ethics committees (RECs). As well as RECs, UNESCO's guidelines cover various forms of bioethics committees, however, namely policy-making or advisory committees, health professional association committees and healthcare or hospital ethics committees. (See UNESCO, “Guide No 1: Establishing Bioethics Committees.”)

<sup>87</sup> UNESCO, “Ethics Education Programme (EEP),” [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=6199&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=6199&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 22 June 2007); Solbakk, op cit.

<sup>88</sup> The relevant articles are: UDHR, articles 20, 21 and 23; IDHGD, articles 6 (a), 23 (a) and 24; and UDBHR, articles 18 (2 and 3), 19 (d), 22 (1) and 23 (1).

<sup>89</sup> Interview with F\_01.



subsequent update read, “During 2006-2007 priority has been given to South-East Europe and part of the Arab region (Gulf region).”<sup>90</sup> Nevertheless, the programme has been active in Africa, the following example serving to illustrate how it is developing. In October 2005, despite being in the throes of planning for a regional centre for bioethics (see 6.3.2.3), the UNESCO Bioethics Chair for Kenya was unaware of the EEP.<sup>91</sup> Less than two years later, the EEP ran a pilot teacher training course at his university, where the centre had been launched a few months earlier.<sup>92</sup> Interviewees were mixed in their reception of the EEP. Some thought that, because there were already several initiatives in ethics, UNESCO would have to find a niche. The head of a research institute in Kenya commented, “Every organisation seems to be organising capacity building in ethics, which you can't say is a bad thing, but I just wonder how much of it is duplicated, how high quality some of it is and how well coordinated everything is.”<sup>93</sup> Perhaps UNESCO has found its niche by focusing on the training of university ethics teachers (as the participant quoted above in regard to GEObs intimated was necessary) rather than REC members, at whom most ethics courses are aimed. (Note, however, that the possible duplication of initiatives notwithstanding, several interviewees identified a need for more training for RECs in both Kenya and South Africa; see 6.3.2.3.)

The third activity is awareness-raising about ethics among the general public, with a view to ensuring that civil society engages with policy-makers and experts in ethical debate around science and technology. This is done primarily through the “Ethics Around the World” conferences mentioned at 5.1.2.2, organised by the Division of the Ethics of Science and Technology in conjunction with UNESCO National Commissions and field offices, as well as academic and research institutions. The conferences have a specific purpose to stimulate debate at national and regional levels and thus focus on topics of

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<sup>90</sup> UNESCO, “Ethics Education Programme (EEP),” [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=6199&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=6199&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 26 August 2005 and 18 September 2007).

<sup>91</sup> Interview with K\_01.

<sup>92</sup> UNESCO, “Ethics Education Programme: Ethics Teacher Training Course,” [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=9448&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=9448&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 20 June 2007).

<sup>93</sup> Interviews with K\_07 (quoted) and SA\_24.

relevance to the host country.<sup>94</sup> If successful they could perhaps help to alleviate the type of public understanding of science and ethics problems highlighted in 5.2.2.

The three declarations call for capacity building in genetics and science and technology as well as in bioethics. Whereas the Bioethics Programme and the Division of the Ethics of Science and Technology within which it sits actively promote ethics, they do not have the expertise or remit to do the same for genetics. A member of the Programme explained that it does not emphasise genetics because of the “division of labour” within UNESCO; basic and life sciences are the mandate of the Science rather than the Social and Human Sciences sector.<sup>95</sup> The Science sector does not appear to be actively promoting the scientific side of the declarations, however. One interviewee, who works with the sector on capacity building in science and technology in Nigeria, had not come across the declarations, for instance.<sup>96</sup> This perhaps points to the need for greater collaboration within UNESCO.

In line with Young’s estimation of IGO resources, the Bioethics Programme’s ambitions for encouraging implementation of the declarations may be somewhat curtailed by funding limitations. During the biennial period 2004-2005, for example, out of UNESCO’s USD 610 million budget for its regular programme, the amount devoted to “ethics of science and technology, with emphasis on bioethics” was just over USD 3.25 million. As the “principal priority” of the Social and Human Sciences Major Programme, this represented 26 per cent of the amount dedicated to activities (excluding cross-cutting projects), compared to 15.3 per cent in the previous biennium.<sup>97</sup> For 2006-07 funding for both the major programme and the ethics section was slightly reduced, although ethics remained the principal priority and its percentage share rose to 30 per cent.<sup>98</sup> To give some idea of how these figures might translate into practical outcomes, in a 2004 document the foundation

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<sup>94</sup> ten Have, *op cit*, 347.

<sup>95</sup> Interview with F\_01.

<sup>96</sup> Interview with K\_04.

<sup>97</sup> UNESCO, “32C/5: Approved Programme and Budget 2004-2005,” (Paris: 2004), 13-14 and 147.

<sup>98</sup> UNESCO, “33C/5: Approved Programme and Budget 2006-2007,” (Paris: 2006), xiii-xiv and 123-124.



and running costs of GEObs over three years were projected at nearly USD 3.4 million (hence funding from external sources was being sought).<sup>99</sup>

It might be that the GGI, if established, could complement UNESCO's capacity building efforts. The proposed network's aims in terms of biotechnological capacity building are strikingly similar to those articulated in the relevant articles of the UNESCO declarations, as shown in 2.3.4.3. If UNESCO does not have the capacity to promote the fulfilment of these articles, the GGI might provide a means, particularly as another of its aims would be to explore "alternative financing options."<sup>100</sup> Through its projected broad membership, the GGI might also enable UNESCO to reach a wider audience in its awareness-raising efforts, given that to "raise public awareness and understanding" was one of TJCB's original objectives in suggesting the network.<sup>101</sup> Whether such a partnership is likely is explored further below.

### 6.2.2 Duplication of activities

Chapter 3 described how, in an *ad hoc* international system, the mandates and programmes of IGOs have a tendency to overlap. This tendency has been mitigated to some extent in bioethics and genetics through the formation of the United Nations Inter-Agency Committee on Bioethics. The committee was initiated by UNESCO, expressly to avoid duplication and promote information exchange among its membership, which is made up of mainly UN agencies but also, at UNESCO's suggestion, other relevant regional and international IGOs.<sup>102</sup> According to the Director-General of UNESCO, this

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<sup>99</sup> UNESCO, "Social and Human Sciences: Guide to Partnerships," 53. This document was seeking to attract funding partnerships for various projects.

<sup>100</sup> Dowdeswell *et al*, *op cit*, 138.

<sup>101</sup> *Ibid*.

<sup>102</sup> Interview with F\_01; UNESCO, "Report of the Third Session of the IGBC," 9-10. The UN members include the Office of the High Commissioner for Human Rights, the International Labour Organization, the Food and Agriculture Organization, the World Intellectual Property Organization and WHO. The non-UN associate members include the European Commission, the Council of Europe, the Organization for Economic Cooperation and Development, the Arab League Educational Cultural and Scientific Organization and the International Centre for Genetic Engineering and Biotechnology. (*Ibid*, 9.) Abbing recommended this kind of coordination in an article on the UDHGHR (1997) and similar texts: "Several international organisations are

action has confirmed the organisation's role as a "catalyst for international cooperation" in the field of bioethics.<sup>103</sup> One interviewee, a member of the SARETI training programme, described why this type of cooperation is needed, given the proliferation of ethics initiatives:

I think there are quite a lot of parallel activities going on globally—not maybe all as wide in scope as the UNESCO one, but, for example, working with UNAIDS and WHO and the EU—and there seem to be lots of parallel initiatives to set up guidelines, to create networks, to create inventories. And I suppose initially it's going to be a good thing, but ideally one day some of them should be collapsed, because it's obviously quite expensive. But I think the good thing is that ethical issues in research generally are suddenly being quite substantially funded and I think that's quite important and especially in developing country related stuff.<sup>104</sup>

Perhaps the UN agency with which UNESCO's bioethics and genetics activities might be seen to overlap the most is the World Health Organization. As mentioned in Chapter 2, WHO produced an influential report in 2002 entitled *Genomics and World Health* (after UNESCO's 1997 declaration on the human genome had been adopted and during the negotiations for the 2003 human genetic data declaration). This described WHO as "in a position to adopt a crucial leadership role in bioethics," one duty of which would be to "exercise its normative function for setting standards and guidelines and harmonization of procedures," partly through helping member states to regulate genomics.<sup>105</sup> WHO has indeed been active in bioethics and genetics, through its Ethics and Health Initiative, launched in October 2002. The Initiative's planned work for 2005 to 2006 included capacity building with member states in research ethics review, promoting collaboration between national bioethics bodies and looking at ethical and cultural issues in human genetics and genomics.<sup>106</sup> While all these activities would seem to duplicate to a large

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involved with the same subject [legal and ethical issues in genetics and transplantation medicine]. From a point of view of effectiveness, efficiency and transparency it would be more fruitful if international discussions could be centered around a particular subject, rather than being framed according to the statutory mandate of an international organisation. Bringing together the various international organisations involved to discuss on equal footing a topical issue avoids a shattering of the debate, and guarantees an integrated approach of all aspects involved through the input of the particular focus of each single organisation involved." (Abbing, "New Developments in International Health Law," 155.)

<sup>103</sup> UNESCO, "Report by the Director-General on the Execution of the Programme Adopted by the General Conference," 39.

<sup>104</sup> Interview with SA\_15.

<sup>105</sup> WHO, *Genomics and World Health*, 8 and 10-11.

<sup>106</sup> This was the latest information on the initiative available on the WHO website as of August 2007.



degree the work that UNESCO has been doing, some of them have in fact been carried out in partnership by the two organisations and it is the Initiative that represents WHO on the Inter-Agency Committee, which played an active role in the elaboration of the UDBHR (see 5.1.2.2).<sup>107</sup> This belies the claims of some of those writing in the *Developing World Bioethics* special issue on the UDBHR that, in promulgating the declaration, UNESCO was encroaching on the mandate of WHO<sup>108</sup>; rather, the organisations' programmes appear to have been mutually reinforcing, as per Young's observations on international institutions.

Given the pronounced coherence between the aims of UNESCO and the proposed GGI, particularly in terms of genetics capacity building and awareness raising, collaboration between UNESCO and TJCB might be expected. This does not appear to have occurred, however. TJCB barely mentions the UNESCO declarations in its publications on the GGI, although in the final paper, drawing on Slaughter's work, it recognised that "networks can exist alongside more traditional international organisations."<sup>109</sup> The UNESCO Bioethics Programme would welcome the opportunity to be involved in the proposed network, as this would represent a marriage between "political initiative" and "practical expertise."<sup>110</sup> That this cooperative model might be possible was also articulated by a Kenyan interviewee who had had previous contact with TJCB. She envisaged UNESCO providing the necessary political platform for the domestication of norms and the GGI garnering a wider audience: "Given intergovernmental processes have their limitations in getting out to civil society and private actors, the Toronto initiative [GGI] might well reach more the

<sup>107</sup> UNESCO, WHO and the Council of Europe contributed to meetings on bioethics and research ethics in Cyprus and Lithuania in May 2004. (WHO, "Ethics and Health 2005/2006: Programme of Work," 1, 2, 3, 4 and 6.)

<sup>108</sup> See Landman and Schüklenk, *op cit*, iii and Williams, *op cit*, 212. ten Have has responded in a *SciDevNet* article that the journal's contributors were perhaps not *au fait* with how UN agencies work. Andorno has written a paper directly answering the *Developing World Bioethics* criticisms, in which he highlights the work of the Inter-Agency Committee, defends UNESCO's activities in bioethics on account of its educational, scientific and cultural mandate and describes how the work of UNESCO and WHO can "perfectly coexist," because UNESCO tends to elaborate general norms, whereas WHO produces more technically focused guidance. (Priya Shetty (quoting ten Have), "UNESCO Guidance on Ethics and Human Rights Slammed," *SciDevNet* (6 September 2005), [www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=2337&lan](http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=2337&lan) (accessed 16 September 2005; Andorno, "Global Bioethics at UNESCO," 151-152.)

<sup>109</sup> Dowdeswell *et al*, *op cit*, 138. References to the UDHGHR have been found in two of TJCB's publications on the GGI: Acharya *et al*, *Genomics and Global Health*, 41 and Thorsteinsdóttir *et al*, "Genomics Knowledge."

<sup>110</sup> Interview with F\_01. Note that in 2004 UNESCO awarded its biennial Avicenna Prize for Ethics in Science to Abdallah Daar, a key proponent of the GGI. (ten Have, *op cit*, 348.)

unreachables.”<sup>111</sup> Echoing Young, a second participant who had connections with TJCB thought that an element of competition or overlap between the two initiatives (and indeed others) was not necessarily counter-productive and could serve to stimulate progress and eventually lead to greater cooperation.<sup>112</sup> Others expressed reservations about the proposed GGI, because of the potential overlap with existing programmes such as those of UNESCO and WHO. Particularly in the South, resources are limited and people have many calls upon their time, thus they do not want to become involved in several projects offering more or less the same things.<sup>113</sup>

### 6.2.3 Enforcement

UNESCO pursues the programme of encouragement outlined in 6.2.1 because it does not have the power to compel its member states to adopt the declarations. Lenoir’s words on the draft UDHGHR (1997) illustrate the limitations: “The idea of the IBC is to propose a Declaration which could serve as a reference, a pattern or a source of inspiration to the States *willing* to adopt legislation on bioethics”<sup>114</sup> (*italics added*). A member of the Bioethics Programme lamented that the organisation is blamed by some for the lack of implementation of the declarations, when in fact it “cannot do much more than what the member states allow us to do.”<sup>115</sup> As this section shows, there has been a reluctance among states to even self-report to UNESCO on their genetics and bioethics activities.<sup>116</sup>

Early in the formulation of the UDHGHR (1997), it was decided that if the declaration was to have a “real impact” a follow-up mechanism would be needed (that is, a system of

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<sup>111</sup> Interview with K\_18.

<sup>112</sup> Interview with SA\_09.

<sup>113</sup> Interviews with K\_07, K\_16, SA\_08, SA\_12 and SA\_30.

<sup>114</sup> Lenoir, “Bioethics and UNESCO,” 12-22.

<sup>115</sup> Interview with F\_01.

<sup>116</sup> Allyn Taylor argued in 1999 that the lack of a formal supervisory mechanism for the UDHGHR (1997) was of “significant concern.” He recommended that self-reporting by states on their implementation of the declaration be combined with fact-finding and review by an independent body, predicting that the “growing sense of urgency” on the need for international cooperation on genetics might serve to “soften national opposition to substantial organizational supervision under a voluntary auditing process.” The negotiations for the UDBHR (2005) would suggest otherwise. (Taylor, *op cit*, 480, 513, 527 and 531.)



implementation review or SIR; see 3.5.3).<sup>117</sup> The implementation guidelines thus stipulated that an evaluation should be carried out five years after the adoption of the declaration.<sup>118</sup> The IDHGD (2003) similarly suggests that states should submit reports to the IBC and IGBC on their implementation of the declaration and the IBC's early recommendations on what became the UDBHR (2005) were that it should include a similar proviso.<sup>119</sup> Whereas the 2002 evaluation of the UDHGHR duly took place in the form of a questionnaire, the proposals for the two later declarations met with resistance from member states (contrary to the trend identified by Victor *et al*, that states are becoming more favourably disposed to SIRs). At the January 2005 IGBC and IBC meetings (which discussed possible implementation guidelines for the IDHGD as well as the text of the draft UDBHR), several government representatives felt that reporting mechanisms were inappropriate to non-binding instruments, as did those attending the IGE meeting in June 2005.<sup>120</sup> According to a member of the Bioethics Programme, the reaction of member states to the IBC's initial suggestion that the UDBHR should specify biennial reports was, "Well, that's out of the question."<sup>121</sup>

This lack of a reporting mechanism for both the IDHGD (2003) and UDBHR (2005) would seem to render them weaker instruments than their predecessor. In reality, however, it makes little difference, because the 2002 evaluation exercise on the UDHGHR (1997), like many SIRs, was something of a failure (despite being deemed an "essential ingredient" of UNESCO's bioethics work by the Director-General).<sup>122</sup> More than 2000 questionnaires were sent to states, IGOs, NGOs, national ethics committees, universities and academic institutions, the private sector and prominent individuals. Since only 100 or

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<sup>117</sup> UNESCO, *Birth of the Universal Declaration on the Human Genome and Human Rights*, 38.

<sup>118</sup> UNESCO, "The Universal Declaration on the Human Genome and Human Rights: From Theory to Practice," 10.

<sup>119</sup> IDHGD, article 25; UNESCO, "Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics," 12.

<sup>120</sup> The states most vocal in their opposition to periodic reporting were the United States, Canada, Germany and India. (IGBC and IBC meetings, Paris, 24 to 28 January 2005, personal observations; UNESCO, "Second Intergovernmental Meeting of Experts: Final Report," 8.)

<sup>121</sup> Interview with F\_01.

<sup>122</sup> UNESCO, "Report by the Director-General on Action to be Taken in the Light of the Round Table of Ministers of Science on Bioethics (22-23 October 2001)," 2.

so questionnaires were returned, however, the results were of limited significance.<sup>123</sup> The Bioethics Programme representative felt that the process was too time-consuming, given the poor response rate. He described how as a secretariat they are in something of a no-win situation: “They [member states] don’t want to be compelled to report on what they do. At the same time they’re always asking us, ‘How is the declaration impacting the member states?’” He hopes that GEObs will enable them to gather information on the implementation of the declaration independently of political processes and thus in a way that is non-threatening to member states.<sup>124</sup>

There is very little in the publications on the proposed GGI to indicate at whom its norms and principles would be aimed and how these might be upheld. Perhaps TJCB hopes that the states ‘underpinning’ the network would enact legislation. This begs the question, what would differentiate the GGI’s norms from international declarations? It is not clear that the network would be in a better position to ensure compliance than its UN-based counterpart, unless its broader membership would mutually enjoin and support adherence. Although its structure would be based partly on Rischard’s GIN model, there is no mention of ‘naming-and-shaming’ renegade actors. Perhaps, like UNESCO and Slaughter, it would be mainly concerned with positive measures such as capacity building (see 3.5.3).

This section has examined UNESCO’s efforts to ensure that member states take up its declarations on genetics and bioethics, as well as the likelihood of the proposed GGI upholding its norms and achieving its aims. The next section turns to the national level, to see whether these efforts are paying dividends.

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<sup>123</sup> UNESCO, “Report of the Third Session of the IGBC,” 8-9.

<sup>124</sup> Interview with F\_01.



## 6.3 NATIONAL IMPLEMENTATION AND ENFORCEMENT

As demonstrated in 6.1.1.3, all three UNESCO declarations require states to take “all appropriate measures” to effect their principles at national level. 6.3.1 assesses how far the member states in general have fulfilled this role, while 6.3.2 looks at the specific cases of Kenya and South Africa. The latter highlights where the two countries are implementing certain principles particularly well and thus could provide examples of good practice for other states, as well as areas in which they need further guidance or support, which UNESCO or the GGI might be able to provide.

### 6.3.1 Adoption by member states

If the UNESCO declarations are not to “remain paperwork,” as non-binding instruments they must be effected by states.<sup>125</sup> Precisely because they are non-binding, however, there is no obligation on states to do so. That declarations can only persuade rather than compel states to modify their laws was reiterated by an official at the Kenyan Ministry of Foreign Affairs. A South African ethicist likewise said that as “merely declarations” the UNESCO instruments serve to “remind governments of their responsibility.”<sup>126</sup> The UDHGHR (1997), as the oldest of the three, might be expected to have been enacted to the greatest degree. In this regard, at a Round Table at the 2001 UNESCO General Conference, 53 ministers of science (or their equivalents) made the following statement:

In conclusion, we, the participating and represented ministers of science:  
(i) undertake to participate actively in the promotion of the principles set out in the Universal Declaration on the Human Genome and Human Rights and in its implementation, in particular by drawing inspiration from it in the formulation of our legislation or regulations, and by considering possible extensions to the Declaration when it is evaluated in 2002-2003.<sup>127</sup>

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<sup>125</sup> ten Have, *op cit*, 343.

<sup>126</sup> Interviews with K\_30 and SA\_37 (quoted) respectively.

<sup>127</sup> UNESCO, “Bioethics: International Implications,” 12.

Since very few countries responded to the evaluation, as demonstrated in 6.2.3, it is difficult to measure whether they have fulfilled this undertaking (the claim of the 2003 IDHGD notwithstanding, that its predecessor had received “firm support” internationally and had been adopted by member states within their legislation, regulations or ethical codes<sup>128</sup>). The IBC’s 2001 paper on solidarity between developed and developing countries reported a paucity of efforts to fulfil articles 17 to 19 of the declaration, on disease research, knowledge sharing and capacity building: “States rapidly recognized the implications of the new scientific advances, but they have not always been so prompt in undertaking projects of solidarity and international co-operation as set out in the Universal Declaration on the Human Genome and Human Rights.”<sup>129</sup>

Lack of information from member states is not the only obstacle in assessing how far the declarations are being implemented at national level. Even when states enact legislation, it is difficult to measure how far this is a direct response to the declarations. A member of the Bioethics Programme averred that it is whether the declarations are being adhered to that is important, not whether this is being done deliberately or not: “Even if we don’t know if it’s *post-* or *propter-* the declarations, it is just what we want, because UNESCO is making the declarations to have more policies in the area of genetics, whether or not it’s our initiation of the whole process.”<sup>130</sup> If it is not the declarations that are inspiring regulatory innovations, however, it can be questioned whether they are really filling a gap as UNESCO claims.

Some states may be taking up the declarations’ principles selectively, or putting their own interpretations on them. Such adaptability could be seen as a weakness or a strength.<sup>131</sup>

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<sup>128</sup> IDHGD, Preamble.

<sup>129</sup> UNESCO, “Report of the IBC on Solidarity and International Co-operation between Developed and Developing Countries concerning the Human Genome,” 14.

<sup>130</sup> Interview with F\_01.

<sup>131</sup> Harmon writes of the UDHGHR (1997), “By its frequent deference to domestic lawmakers, it fails to provide a universal response that will guard against piecemeal legislation and a ‘race to the bottom’.” (Harmon, *op cit*, 37.) A geneticist in South Africa similarly commented on the declarations, “They seem to take the way out always of talking of the regulations in the individual countries or the laws of the individual countries and so on. So it can only be an advisory sort of document and I think that’s fine, but it would seem as though they don’t have any teeth.” (Interview with SA\_18) Andorno, by contrast, believes that to impose a comprehensive legal framework on countries with differing sociocultural backgrounds would be both impossible and unfair.



UNESCO, for its part, endorses national contextualisation. In a paper outlining all UNESCO's bioethics activities, Henk ten Have, head of the Division of the Ethics of Science and Technology, writes with regard to the UDBHR's articles on consent and social responsibility: "As principles they are universally adopted, but in practice their application must be tailored in multiple ways to accommodate different types of research and health care, categories of patients and problems, and cultural settings and traditions."<sup>132</sup> Participants in Kenya and South Africa saw contextualisation as important if the declarations are to be adopted effectively. A scientist who advises both UNESCO and the Kenyan government believed it would be "dangerous" to adopt the declarations without translating them into "what is happening locally."<sup>133</sup> Several others said that universal principles should not be embraced unthinkingly; working out their practical application in particular contexts is often the most challenging aspect of implementing international instruments.<sup>134</sup> One long-standing ethics committee member went further, believing there to be too much variation between countries for universal norms to be useful. He asserted, "I believe strongly that national, local ethics guidelines are the things to follow."<sup>135</sup>

### 6.3.2 Adoption in Kenya and South Africa

Both Kenya and South Africa are upholding the UNESCO declarations to a greater or lesser extent, according to their regulatory frameworks for genetics and bioethics. This section outlines the situation in each country in turn, before looking at areas where they might benefit from guidance or support. Interestingly, although the two national frameworks are quite different, the challenges highlighted by interviewees from both

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(Andorno, "Biomedicine and International Human Rights Law," 962.) Echoing Victor *et al*, Christian Byk sees the UDHGHR's non-binding flexibility in a positive light: "It facilitates adhesion to the Declaration by those states which have difficulty satisfying the implementation of the principles, but which intend to go further that way." (Byk, "A Map to a New Treasure Island," 237.)

<sup>132</sup> ten Have, *op cit*, 342-343.

<sup>133</sup> Interview with K\_13.

<sup>134</sup> Interviews with K\_15, K\_26, SA\_10, SA\_17, SA\_24 and SA\_25.

<sup>135</sup> Interview with SA\_19.

countries are very similar. As mentioned in Chapter 2, both Kenya and South Africa adopted national guidelines on bioethics in 2004, *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya* and *Ethics in Health Research: Principles, Structures and Processes* respectively.<sup>136</sup> As might be expected, these documents articulate well-established bioethical principles such as informed consent, autonomy, privacy and confidentiality and the need for risk/benefit analyses. They also deal to some degree with several of the issues discussed in Chapter 2 around the ethical dilemmas generated by genetics and research in developing country contexts. In this they draw mainly on the World Medical Association's *Declaration of Helsinki* and the CIOMS guidelines, but seemingly not at all on the UNESCO declarations.<sup>137</sup>

### 6.3.2.1 Kenya

The regulatory framework for bioethics in Kenya is far from clear. Under the 1979 Science and Technology Act, the National Council for Science and Technology (NCST) is to advise the government on “all matters related to research.” It has ultimate control over what research takes place in Kenya and the power to ensure it is conducted ethically. Some of these powers are devolved to institutional ethics committees, such as that of the Kenya Medical Research Institute (KEMRI). The 2004 ethical guidelines named above (produced by NCST) describe this system as “weak with many loopholes.”<sup>138</sup> A member of the Council explained that ethics were not a major concern when the Science and Technology Act was promulgated and thus do not feature prominently within it. At the time

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<sup>136</sup> Both countries also have more specific guidelines, on HIV/AIDS vaccines and clinical trials. These are the *Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines* (2005), the *Guidelines on Ethics for Medical Research: HIV Preventive Vaccine Research* (produced by the Medical Research Council of South Africa and adopted as national guidelines) and the *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa*. Like their more general counterparts, these guidelines have sections on standard ethical principles and issues pertinent to developing countries. This thesis draws predominantly on the more general guidelines, however.

<sup>137</sup> NCST, *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya*, 19; Department of Health, *Ethics in Health Research*, 55; interviews with K\_15, K\_17, K\_19, K\_21, SA\_24 and SA\_35. Note that the NCST guidelines reference the 1993 version of the CIOMS guidelines rather than the more recent 2002 version. The UNESCO declarations are not listed among the references for either document.

<sup>138</sup> NCST, op cit, 2.



of fieldwork, NCST had been pushing for many years for the Act to be updated to include current ethics issues, but as several acts were awaiting amendment this was likely to take some time.<sup>139</sup> The KEMRI ethics committee has gone one step further and recommended a “stand alone” act for biomedical research involving humans, seeing the Science and Technology Act as too generalised.<sup>140</sup> The KEMRI-Wellcome Trust Collaborative Programme at Kilifi was using the NCST guidelines at the time of interview, but was assuming these were still in draft, having not heard otherwise. On being asked whether the guidelines were legally binding, one member of the Programme commented that this “would be quite a useful thing to know.”<sup>141</sup>

Relatedly, the fieldwork revealed some ambiguity as to the status and purpose of certain ethics committees in Kenya. Most interviewees agreed that, in practice, the KEMRI committee functioned as a national ethics committee.<sup>142</sup> Indeed, the KEMRI website reads, “The Committee is accepted by the Ministry of Health as a National Ethical Review Committee.”<sup>143</sup> It seems strange, then, that this same ministry has also set up its own ethics committee. In January 2001, following recommendations in the National Health Sector Strategic Plan, it established a Health Standards and Regulatory Services Department to, among other things, “provide the priority medical research agenda” and “review medical research protocols in Kenya.”<sup>144</sup> As noted in 2001 by Daniel arap Moi, then president of Kenya, this new department’s mandate included the launch of a national ethics committee.<sup>145</sup> The National Medical Research, Ethics and Traditional Medicine Committee was duly created in 2002, ostensibly including KEMRI and NCST among its

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<sup>139</sup> Interview with K\_21.

<sup>140</sup> Interview with K\_19.

<sup>141</sup> Interviews with K\_06 (quoted), K\_07 and K\_09.

<sup>142</sup> It seems that the KEMRI committee, as one of the institutional committees to which NCST has devolved some of its duties, reviews protocols that do not fall under any of the other NCST approved committees and thus to all intents and purposes has become a national ethical review committee (that is, it does not review only research carried out within KEMRI). (Interviews with K\_07, K\_15, K\_19, K\_21, K\_22 and K\_25.)

<sup>143</sup> KEMRI, “Scientific and Technical Committees,”

[www.kemri.org/Scientific%20and%20Technical%20committee.htm](http://www.kemri.org/Scientific%20and%20Technical%20committee.htm) (accessed 23 November 2007).

<sup>144</sup> Ministry of Health, “First National Congress on Quality Improvement in Health Care, Medical Research and Traditional Medicine,” 1-2 (quoted); interview with K\_27.

<sup>145</sup> Ministry of Health, “First National Congress,” 7.

membership.<sup>146</sup> On the relationship between this new committee and the KEMRI committee, a member of the latter said:

The Ministry of Health wanted to start their own. It would be a year ago, we all met together, the Director of Medical Services and some visitors from the Walter Reed and they said that they wanted to start their own. But, notwithstanding, we decided we would not wait for them. If they started their own, that's fine and they'd tell us how we would relate to them. But we consider ourselves the National Ethical Review Committee.<sup>147</sup>

She also explained that, as a consequence of the proliferation of committees, it is possible that some research goes unapproved, because people can plead, "I got confused, I didn't know where to go, so I decided not to go anywhere."<sup>148</sup> A 2003 Ministry of Health report similarly acknowledged that stakeholders needed to be educated on the relationships between its new committee, KEMRI and NCST.<sup>149</sup>

Despite the profusion of committees described above, in October 2005 the National Commission for UNESCO, with the Bioethics Chair, was looking to form a National Bioethics Committee.<sup>150</sup> Their rationale was the same as that behind the Bioethics Programme's Assisting Bioethics Committees initiative (see 6.2.1): they would start with a committee and perhaps push for a bill "later on."<sup>151</sup> (Interestingly, however, the Chair was unaware of UNESCO's guidelines on how to set up just such a committee.) A member of the Commission did not think the new committee would overlap with Kenya's pre-existing ones because it would engage primarily in sensitising people about bioethics and the three UNESCO declarations in particular, rather than ethical review. He said, "I don't think there's any other committee that is doing that." Furthermore, it would include among its membership representatives from the relevant government bodies.<sup>152</sup> Not everyone was convinced, however. A member of NCST welcomed the idea of working with UNESCO to

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<sup>146</sup> Ministry of Health, "Second National Congress on Quality Improvement in Health Care, Medical Research and Traditional Medicine."

<sup>147</sup> Interview with K\_17. "Walter Reed" refers to USAMRU-K, the Kenyan branch of the US-based Walter Reed Army Institute of Research.

<sup>148</sup> Ibid.

<sup>149</sup> Ministry of Health, "Second National Congress."

<sup>150</sup> Interviews with K\_01 and K\_16.

<sup>151</sup> Interview with K\_01.

<sup>152</sup> Interview with K\_16.



promote knowledge sharing and capacity building, but thought that a new committee was unnecessary.<sup>153</sup>

Whereas there appear to be two parallel systems for ethical review in Kenya, there is little regulation targeted at human genetic research. The *2004 Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya* do not cover genetic research specifically. At the time of fieldwork, Kenya was awaiting the adoption of a Biosafety Bill, which was first promulgated in 2003 and focuses on agricultural biotechnology.<sup>154</sup> Interviewees could see neither the Bill being expanded to cover human genetics, nor a separate bill on the human side being drawn up in the near future.<sup>155</sup> Thus it would appear that the two genetics declarations, the UDHGHR (1997) and the IDHGD (2003), are unlikely to be adopted into Kenyan legislation. There is perhaps a need for regulation in this area, however, particularly on who should own and profit from human samples and data, in the wake of scandals in the recent past.<sup>156</sup>

Those connected with UNESCO explained why it might be a long time before the declarations are adopted into Kenyan law. A member of the National Commission for UNESCO outlined the difficulties of first raising the necessary political will: "How are you going to sell it to your country? How do you advise? Do you wait until there's a problem, then you say, 'Okay, let's refer to...'. Or do you need to sensitise people in advance?"<sup>157</sup> Even if this was achieved, the legislative process is a slow one, involving negotiations between several ministries. It can also be somewhat capricious. The scientist quoted above who advises both UNESCO and the government warned that if the desk officer

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<sup>153</sup> Interview with K\_21.

<sup>154</sup> As of August 2007, the Bill was about to be passed, although it still faced opposition from peasant farmers and critics of genetically modified organisms. (ASNS Kenya Correspondent, "Kenya's Biosafety Bill Faces Opposition," and Leakey Sonkoyo, "Kenya Parliamentarians Could Pass Biosafety Bill," *Africa Science News Service* (21 August 2007).

<sup>155</sup> Interviews with K\_01, K\_13, K\_18 and K\_21.

<sup>156</sup> Ownership issues were raised by the Kenyan delegation at the January 2005 IGBC and IBC meetings in Paris (personal observation). One interviewee described issues around ownership of genetic data as "complex," particularly in terms of commercial interests and feeding back to communities (K\_05). Another said that community leaders had recently been raising the ownership question (K\_09). Several Kenyan participants gave examples of research projects that were considered to have collected human genetic samples in an unethical manner (K\_01, K\_10, K\_11, K\_12 and K\_17). These examples did not include any of the projects visited for the purposes of this thesis.

<sup>157</sup> Interview with K\_16.

assigned the portfolio for adoption of a declaration is a “middle of the roader,” nothing might happen for several years.<sup>158</sup> Also, as pointed out by the National Commission representative, if the government changes, sensitisation of ministers has to begin all over again.<sup>159</sup> In spite of such difficulties, the Commission believes the sensitisation of policy-makers worth pursuing, it being one of the reasons behind the establishment of the regional bioethics centre (see 6.3.2.3).

#### **6.3.2.2 South Africa**

The South African bioethics framework is somewhat more coordinated than the Kenyan one. According to the National Health Act (2003), implemented by the Department of Health, a National Health Research Ethics Council is to carry out a variety of tasks, including writing guidelines for research ethics committees (RECs) and setting norms and standards for research with humans; disciplining those found to be in violation of these guidelines or norms; registering and auditing RECs and adjudicating complaints about them; and advising the national and provincial departments of health on issues in research ethics.<sup>160</sup> In fact, the guidelines and norms, the *Ethics in Health Research: Principles, Structures and Processes* (2004) mentioned above, were written by an interim committee. This committee subsequently disbanded and, at the time of fieldwork in early 2006, the permanent council had not yet been appointed (an invitation for nominations had been issued).<sup>161</sup> This meant that for a few years there was no national body overseeing bioethics, although accreditation of RECs (both public and private) was ongoing. It seems that the ethical guidelines are to be supported by formal statutes, as in February 2007 the Department of Health invited comment on proposed regulations

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<sup>158</sup> Interview with K\_13. K\_16 also said that the rate of legislation in Kenya had been slow, thus the system was clogged with pending bills.

<sup>159</sup> Interview with K\_16.

<sup>160</sup> Clause 72 (6). Republic of South Africa, National Health Act, 74.

<sup>161</sup> Government Gazette, “Invitation to interested parties to nominate persons for appointment to the National Health Research Ethics Council,” No 304 (24 February 2006), 81-82.



relating to research on human subjects, an adjunct to the National Health Act. These regulations articulate the principles outlined in the guidelines in a shortened form.<sup>162</sup>

The 2004 ethical guidelines contain chapters on human genetic research and the use of human samples that mirror many of the articles of the IDGHD (2003). The chapter on human genetic research recognises that individuals share genes with relatives and other members of the population and may be subject to genetic discrimination or stigmatisation. It stipulates, "Researchers should consider the social and cultural significance of their research, especially in the areas of complex socially significant characteristics and the genetic characteristics of collectivities."<sup>163</sup> In addition, in January 2007 the government invited comment on proposed "Regulations regarding the use of human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics," another adjunct to the National Health Act.<sup>164</sup> These, together with the ethical guidelines, give comprehensive instruction on the collection, processing, storage and use of human genetic data. The proposed regulations relating to research on human subjects also contain a chapter on genetic research. Despite the synergies, the UNESCO genetics declarations do not appear to have inspired the human genetics chapter of the ethical guidelines, as they are not cited in the guidelines' list of key international texts.<sup>165</sup> In the case of the proposed regulations regarding DNA, RNA and other human samples, what the influence of the declarations has been is unclear. One member of the team that drafted the regulations was unfamiliar with the UNESCO instruments, whilst another said

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<sup>162</sup> Government Gazette, "Regulations relating to research on human subjects," No 135 (23 February 2007), 10-16. Comments were to be submitted by 23 April 2007. As of August 2007 the regulations did not appear to have been adopted.

<sup>163</sup> Department of Health, *op cit*, 42-45. Collectivities are "groups distinguished by: common beliefs, values, social structures and other features that identify them as a separate group; customary collective decision-making according to tradition and beliefs; the custom of leaders expressing a collective view; members of the collectivity being aware of common activities and common interests." (*Ibid*, 28.)

<sup>164</sup> Government Gazette, "Regulations regarding the use of human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics," No 7 (5 January 2007), 3-11.

<sup>165</sup> As the guidelines were published in 2004, it is possible that the chapter on genetic research had already been drafted when the IDHGD was adopted in October 2003.

that the 1997 and 2003 declarations had “definitely assisted the writing of the regulations for the genetics that’s going to come through soon.”<sup>166</sup>

The proposed regulations on DNA, RNA and other human samples state that intellectual property rights shall apply to all forms of genetic research, except stem cell research.<sup>167</sup> Several participants supported the idea of genetic information as a public good, particularly as developing countries do not have the capacity to do substantial genome sequencing themselves (although one scientist said that in practice some researchers prefer to put their findings in the public domain only at the end of a study, to coincide with publications<sup>168</sup>). They saw it as important to protect the ideas and products that are the result of research on this information, however, to stimulate innovation.<sup>169</sup> Finding the right balance between propagation and protection is something that the proposed GGI might assist with, one of TJCB’s stated aims for the network being that “the GGI could examine different models of intellectual property protection to optimise social utility while maintaining necessary incentives for discovery.”<sup>170</sup>

As well as the regulations for genetic research that fall under the National Health Act, South Africa has a National Biotechnology Strategy (2001), administered by the Department for Science and Technology.<sup>171</sup> The strategy includes a National Biotechnology Advisory Committee, which was in the final stages of composition at the time of fieldwork. The proposed function of the Committee was to advise the Minister of Science and Technology on the progress of biotechnology development in South Africa, particularly in terms of innovation and commercialisation, but also ethics and legislation. Initially a separate bioethics committee was also planned, but after consultation with the South African Medical Research Council, the Department of Health and experts in the

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<sup>166</sup> Interviews with SA\_04 and SA\_17 (quoted) respectively.

<sup>167</sup> Government Gazette, “Regulations regarding the use of human DNA, RNA *et cetera*,” 10.

<sup>168</sup> Interview with SA\_07.

<sup>169</sup> Interviews with SA\_26, SA\_27, SA\_32 and SA\_33.

<sup>170</sup> Dowdeswell *et al*, *op cit*, 138.

<sup>171</sup> See Department of Arts, Culture, Science and Technology, “A National Biotechnology Strategy for South Africa.” (The Department split into the Department of Arts and Culture and the Department of Science and Technology in 2002.)



field (including a member of the Interim National Health Research Ethics Committee), it was decided that this would only duplicate existing initiatives. Instead, the advisory committee would include ethicists among its members, to keep it informed of relevant bioethics issues or developments.<sup>172</sup>

There may yet be another national level bioethics body formed. On returning from the IGE meeting in June 2005, the chief South African representative recommended in her report to the National Commission for UNESCO that the country should have a central committee to deal with ethics. This committee would engage with the various RECs around the country, to bring them under one 'umbrella' within a virtual structure. National guidelines would "serve as a framing document that's a 'one-stop shop' for anyone wanting to apply to ethics committees to conduct research," thus ensuring that people would be following the same rules, whether they were based within a university, an NGO or any other institution. Thus the committee's mandate would be very similar to that of the National Health Research Ethics Council. Perhaps the two initiatives could be complementary, however, as the portal would also facilitate "livewire discussion" and house a panel of experts who could give insights into various issues pertaining to human rights and bioethics. Whether these recommendations will be taken up is open to question; they had not been at the time of interview in April 2006. The IGE representative said, "The translation post the declaration has been absolutely pathetic and somebody needs to drive it in a forceful sort of way. And I don't believe that the infrastructure is there for that to happen."<sup>173</sup> Thus the active community that Young sees as necessary to stimulate regime implementation appears to be lacking in South Africa.

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<sup>172</sup> Interviews with SA\_28 and SA\_31.

<sup>173</sup> Interview with SA\_23.

### **6.3.2.3 Areas needing guidance or support**

Fieldwork participants identified certain interconnected issues, relevant to both genetic research and research with human subjects more broadly, which are particularly pertinent to Kenya and South Africa. These can be categorised as: protection of research subjects; health development, capacity building and benefit sharing; and ethical review capacity. This section describes how these issues are being dealt with or otherwise by the two countries. As the UNESCO declarations contain norms on how such issues can or should be addressed, it may be that the organisation's Bioethics Programme could offer guidance or support in these areas as part of its ongoing follow-up activities (the relevant articles are indicated for each of the sub-sections below). Some of the activities planned for the GGI may also be relevant.

#### ***Protection of research subjects<sup>174</sup>***

Both Kenya and South Africa decided that national bioethics guidelines were needed partly in order to protect poor and marginalised people from being exploited by unscrupulous researchers. Both sets duly give specific instructions concerning vulnerable groups such as pregnant women and prisoners.<sup>175</sup> Several people saw such provisions as necessary to prevent vulnerable people from being subjected to undue inducement to take part in research projects of no relevance to them.<sup>176</sup> Ethics committees in both countries take particular care that projects which involve research into Africa's "treasure store" of diseases or evolutionary significant DNA are not exploitative,<sup>177</sup> although some Kenyan NGO representatives expressed concern about vulnerable people being asked to give blood samples, for example, without being adequately informed of their rights.<sup>178</sup>

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<sup>174</sup> On vulnerability see UDHGHR, article 17 and UDBHR, article 8; on cultural diversity and pluralism, UDBHR, article 12; and on community engagement, UDBHR, article 6 (3).

<sup>175</sup> NCST, op cit, 2, 10 and 11-14; Department of Health, op cit, Preamble, 24-25, 27-28 and 30.

<sup>176</sup> Interviews with K\_25, SA\_12, SA\_19, SA\_30 and SA\_32.

<sup>177</sup> Interviews with K\_17 (quoted) and SA\_04.

<sup>178</sup> Interviews with K\_10 and K\_11.



One means to guard against exploitation is to engage with the communities within which it is hoped that research will take place. Both the Kenyan and South African guidelines call on researchers to be aware of and respect the cultural traditions of the communities in which they wish to conduct research and to liaise with and seek permission from their leaders where appropriate.<sup>179</sup> Researchers, ethicists, policy-makers, NGO representatives and those with commercial interests alike saw this type of interaction as tremendously important, partly because of the culture in many African societies that decisions should be “ratified communally,” often by chiefs.<sup>180</sup> Almost as many expressed reservations about the ethos of community consent and engagement, however, because defining who or what ‘the community’ actually is and who should be representing it is very difficult. Said one participant, “I think it sounds very nice, but I don’t know how one does it. Often it’s lip service, because I mean the problem even before that is, what is the community, where do you find it?”<sup>181</sup> Another considered that the UDBHR (2005), to be of use, would have to deal with these subtleties.<sup>182</sup> It simply states, however, that for a research project on a group or community, agreement from representatives may be sought, in addition to that of individual participants (article 6).

It seems that guidance on the intricacies of community engagement are lacking, so this might be a ripe subject for follow-up by the UNESCO Bioethics Programme in the form of an IBC report or a training course.<sup>183</sup> One participant suggested that guidelines on ‘community preparedness’, which goes beyond community consent to see what community members think about a proposed research project and what they might want from it, would be useful.<sup>184</sup> This is in fact a practice that the KEMRI-Wellcome Trust Collaborative Programme at Kilifi, Kenya, has spent several years developing, such that

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<sup>179</sup> NCST, op cit, 11 and 14; Department of Health, op cit, 25 and 28.

<sup>180</sup> Interviews with K\_08 (quoted), K\_01, K\_02, K\_04, K\_05, K\_06, K\_09, K\_19, K\_20, K\_25, SA\_02, SA\_04, SA\_12, SA\_13, SA\_15, SA\_21, SA\_30, SA\_32 and SA\_37.

<sup>181</sup> Interview with SA\_16. Those who expressed a similar view were K\_03, K\_07, K\_08, K\_11, K\_18, SA\_10, SA\_19, SA\_33 and SA\_35.

<sup>182</sup> Interview with K\_07.

<sup>183</sup> Note that TJCB, under the Grand Challenges in Global Health programme, has recently brought out a series of papers on ethical, social and cultural issues in doing research in developing countries, which analyse in depth what makes for good practice in community engagement. Thus any IBC report would have to complement these. (The four papers, by Abdallah Daar, Peter Singer and colleagues, appear in *PLoS Medicine* 4 (9) (September 2007): 1440-1459.)

<sup>184</sup> Interview with SA\_24.

communities are involved in the planning of research, in order to ensure it is performed in ways appropriate to the local context.<sup>185</sup> At the time of fieldwork, it had recently set up a network of community representatives from a wide range of backgrounds (some of whom were possibly to join the Programme's Consent Committee), through an exhaustive two-year recruitment process that might perhaps provide a model for other research centres or projects.<sup>186</sup>

*Health development, capacity building and benefit sharing*<sup>187</sup>

The Kenyan and South African guidelines require research to be relevant not only to study populations but also to each country as a whole, by addressing "health needs" and "broad health and development needs" respectively.<sup>188</sup> The South African guidelines deem it necessary for multinational collaborative research to be linked to capacity building in healthcare and economic and educational empowerment in the host country and embrace the social responsibility ethos thus:

With recognition of the role of social conditions in shaping the world, and how privileged people view the world and themselves, comes the realisation that research cannot be considered in isolation. Medical research, health care, conditions of life around the world and how humans flourish may seem disparate, but all are interdependent.<sup>189</sup>

Several participants agreed that research should address the health and development needs of the country in which it is to be conducted.<sup>190</sup> This is something that RECs in both countries consider when reviewing protocols.<sup>191</sup> A member of the KEMRI committee explained that they are not trying to limit basic research, but would like to see this

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<sup>185</sup> Interview with K\_06.

<sup>186</sup> Interviews with K\_06, K\_09 and K\_23. The Consent Committee reviews procedures for obtaining informed consent.

<sup>187</sup> On social responsibility see UDHGHR, articles 12 (b) and 17 and UDBHR, articles 14 and 21 (3); on benefit sharing, UDHGHR, articles 12 (a) and 19 (a, iii), IDHGD, article 19 and UDBHR, articles 15 and 21 (4); and on scientific and technological capacity building, UDHGHR, articles 18 to 20, IDHGD, articles 18 (a and b), 19 (a, v and vi), 23 and 24 and UDBHR, articles 15 (1, e and f), 22 (1) and 24 (2).

<sup>188</sup> NCST, op cit, 13 and 16; Department of Health, op cit, 3.

<sup>189</sup> Department of Health, op cit, 7. That the guidelines should include this ethos is perhaps not surprising, given that Solomon Benatar was on the editorial team. In fact, this passage is almost identical to one from his 2001 commentary in the journal *Bioethics*, "Justice and Medical Research: A Global Perspective" (337; previously quoted at 2.1.3).

<sup>190</sup> Interviews with K\_07, K\_08, K\_14, K\_17, K\_19, K\_25, SA\_08, SA\_09, SA\_17, SA\_19, SA\_21, SA\_32 and SA\_37.

<sup>191</sup> Interviews with K\_17 and SA\_19.



integrated with social aspects: "We would like people to write more practical protocols."<sup>192</sup>

Similarly, the Biotechnology Regional Innovation Centres (BRICs) that fall under the South African National Biotechnology Strategy are not to invest in "purely white elephant science development," but in strategic basic research that addresses national priorities.<sup>193</sup> Through such measures South Africa is embracing what the social responsibility article of the UDBHR (2005) deems to be a "central purpose" of government, the promotion of health and social development.<sup>194</sup>

Some participants did not think health and social development should be a requirement of research, as this could limit basic or innovative research that might have massive long-term but serendipitous benefits.<sup>195</sup> Others thought that there might be more effective means to address poverty than "high-flying scientific studies."<sup>196</sup> Two people questioned the practical applicability of the social responsibility principle. The first, a scientist and ethicist, wondered how far the responsibility extends, given the enormous challenges poverty in the developing world presents:

The needs, in developing countries, are of such a nature, you can't provide it all. And if you don't research, you're also not going to bring something better. So this is a major, major debate. I mean, I have a conflict in my own mind: to what extent do I have responsibility?<sup>197</sup>

The second, a member of an ethics committee in South Africa, approached the problem from a different angle. He said that while his committee was conscious that projects ought to have social value, in reality it would be difficult to reject one that did not, as this would mean turning down funding for the university.<sup>198</sup> These are perhaps issues that could be addressed in the IBC's report on social responsibility and health.<sup>199</sup>

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<sup>192</sup> Interview with K\_17.

<sup>193</sup> Interview with SA\_26.

<sup>194</sup> UDBHR, article 14.

<sup>195</sup> Interviews with K\_09, SA\_12 and SA\_20.

<sup>196</sup> Interview with SA\_03. SA\_18 made a similar comment, although he also said that genetic research might be useful in the long term, in the hunt for effective vaccines, for example.

<sup>197</sup> Interview with SA\_24.

<sup>198</sup> Interview with SA\_10.

<sup>199</sup> As of January 2008, the report was in draft form.

The principle of benefit sharing, like social responsibility, is applied to both specific communities and the wider national contexts in the Kenyan and South African guidelines, particularly in terms of health services and products.<sup>200</sup> RECs in both countries, when reviewing protocols, try to assess the extent to which participants will benefit from a research project.<sup>201</sup> Several interviewees thought it important that communities taking part in research should benefit in some way.<sup>202</sup> One prominent South African bioethicist said:

The question is whether research is ethical if the people and communities who are the subjects of research have not benefited from improvements in their health or their healthcare. If they have not benefited then I am sceptical of how ethical it is to do research in those places.<sup>203</sup>

As with social responsibility, however, some people raised issues with regard to the complexities of actually implementing benefit sharing, in terms of making commitments to provide for communities before the results of research are known and determining exactly who should benefit and for how long.<sup>204</sup> These are difficult issues for ethics committees to adjudicate.<sup>205</sup>

Aside from health services and products, benefit sharing can take the form of capacity building for research. The Kenyan guidelines stipulate that externally sponsored collaborative research should develop research capacity in Kenya.<sup>206</sup> There is relatively little of this type of research taking place in either Kenya or South Africa, however. Geneticists in both countries lamented the fact that, because developing countries are perceived as not having the capacity to deliver, funding for research tends to flow to northern institutions.<sup>207</sup> One commented, "I think there is a lot of talk of goodwill, but they have been slow."<sup>208</sup> There is also insufficient local funding for research.<sup>209</sup>

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<sup>200</sup> NCST, op cit, 5 and 16; Department of Health, op cit, 3, 7 and 9.

<sup>201</sup> Interviews with K\_25, SA\_10, SA\_19 and SA\_35.

<sup>202</sup> Interviews with K\_10, K\_14, K\_18, SA\_04, SA\_12, SA\_13, SA\_17, SA\_19, SA\_25 and SA\_33.

<sup>203</sup> Interview with SA\_09.

<sup>204</sup> Interviews with K\_05, SA\_16, SA\_21, SA\_27 and SA\_35.

<sup>205</sup> Interviews with SA\_10, SA\_15 and SA\_35.

<sup>206</sup> NCST, op cit, 16.

<sup>207</sup> Interviews with K\_05 and SA\_27.

<sup>208</sup> Interview with K\_13.

<sup>209</sup> Interviews with K\_05, K\_10, K\_14 and SA\_27.



Participants generally acknowledged that research capacity building requires the support of developed countries, but had firm ideas about what form that support should take.<sup>210</sup> Firstly, capacity building programmes should be designed with the input of African scientists and policy-makers. One researcher said, “Let the initiative come from our side... If it comes from the other side, the success will be a little bit lower, because it is as if something is brought in.”<sup>211</sup> Secondly, programmes should ideally represent long-term investment, in terms of training, infrastructure and salaried posts, rather than “travel and tourism money,” whereby people are sent abroad for a few months’ training.<sup>212</sup> Ethics committees prefer a project to train people to analyse data in-country where possible, rather than to ship samples abroad.<sup>213</sup> ‘Brain drain’ is an ongoing problem. Even if African scientists train in the South, many are likely to develop their careers in northern institutions.<sup>214</sup>

These are issues that both UNESCO and the proposed GGI, if established, will have to address, as capacity building is promoted in all three declarations and would be a major feature of the GGI’s activities. One example of good practice that they might wish to draw upon is again that of the Kilifi KEMRI-Wellcome Trust Collaborative Programme. Capacity building is its *raison d’être*. Rather than following past models that saw “grateful African institutions” being invited to join northern-led projects, the centre falls under KEMRI management. The long-term vision, stretching over 25 years, is to build up a “cadre of international research leaders” from Kenya and the East Africa region. To achieve this, the centre aims to develop research facilities of international standing and ensure sufficient funding to provide attractive career paths for scientists wishing to stay in Kenya.<sup>215</sup> The South African National Bioinformatics Institute has a similar vision, its “key underpinning” being its aim to bring Africans to a competitive level in bioinformatics.<sup>216</sup>

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<sup>210</sup> Interviews with K\_07, K\_16, SA\_26, SA\_27 and SA\_34.

<sup>211</sup> Interviews with K\_01 (quoted), K\_07 and K\_13.

<sup>212</sup> Interview with SA\_27.

<sup>213</sup> Interviews with K\_17, K\_21, K\_25, SA\_19, SA\_21 and SA\_30.

<sup>214</sup> Interviews with K\_05, K\_10, SA\_20, SA\_26, SA\_28 and SA\_34.

<sup>215</sup> Interviews with K\_05 and K\_07 (quoted).

<sup>216</sup> Interview with SA\_02.

### *Ethical review capacity*<sup>217</sup>

RECs in both Kenya and South Africa have diverse memberships, as stipulated in both the UNESCO declarations and the two sets of national guidelines.<sup>218</sup> Several interviewees highlighted deficiencies in capacity, however, in terms of training and funding. Kenya needs more people with expertise in research ethics, not only to constitute new committees but also to relieve those who sit on existing ones, which are undertrained and overburdened.<sup>219</sup> At the time of fieldwork, there were no suitable courses in East Africa, so people were having to travel to South Africa if they wished to undergo such training.<sup>220</sup> It is not only REC members who require instruction, but also scientists and students; several people commented that Kenya does not have sufficient university courses in research ethics. Should this change, the standard of applications for ethical review might improve. (The pilot training course for university ethics teachers held in Kenya in 2007, under UNESCO's Ethics Education Programme, would seem a promising development in this regard; see 6.2.1.) One participant made a similar comment about South Africa, although it has more university courses than Kenya.<sup>221</sup>

The courses in South Africa that Kenyan REC members have attended are run by SARETI and IRENSA, both sponsored by Fogarty International.<sup>222</sup> Fogarty's rationale is to build capacity for ethical review that is appropriate to the local context. Attendees are primarily members of RECs from Kenya, South Africa and other countries in the sub-Saharan region, but also number scientists, journalists, government officials and people from private sector companies. The aim is to have a good balance of working disciplines, genders and ethnic backgrounds.<sup>223</sup> SARETI runs a Masters programme, whilst IRENSA offers a postgraduate diploma and shorter courses, the latter catering for 75 REC

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<sup>217</sup> The relevant articles are: UDHGHR, articles 5 (d), 16, 19 (a, i), 20 and 23; IDHGD, article 6 (b and c), 23 (a) and 24; and UDBHR, articles 19 (a), 20, 21 (2) and 22.

<sup>218</sup> Interviews with K\_06, K\_09, K\_17, SA\_10 and SA\_19; NCST, op cit, 16-19; Department of Health, op cit, 15.

<sup>219</sup> Interviews with K\_21, K\_25 and K\_27.

<sup>220</sup> Interviews with K\_17 and K\_21.

<sup>221</sup> Interviews with K\_01, K\_02, K\_03, K\_17, K\_19, K\_21 and SA\_17.

<sup>222</sup> IRENSA is the International Research Ethics Network for Southern Africa, based at the University of Cape Town. SARETI is the South African Research Ethics Training Initiative and is run by a collaborative partnership between the University of KwaZulu-Natal, the University of Pretoria and Johns Hopkins University.

<sup>223</sup> Interviews with SA\_09 and SA\_15.



members a year.<sup>224</sup> Although this is impressive, a member of the SARETI teaching staff identified a gap in that neither these programmes nor others teach African philosophical perspectives on ethics. She said, "The one thing that I think is lacking in all these training programmes is that we don't often access African philosophers... because there is definitely a clear distinction between African philosophy and Western philosophy and I think that needs its space."<sup>225</sup> A member of the KEMRI-Wellcome Trust Collaborative Programme at Kilifi detected a similar Western bias. She expressed the hope that, through the Programme (perhaps in conjunction with SARETI), people in Kenya and Africa as a whole might become more engaged in ethical debates and so progress from trying to make guidelines produced in the North work in their settings to taking the "slightly more challenging stance" of developing "new ideas about what the guidelines should be."<sup>226</sup>

Beyond training, another area in which RECs in Kenya and South Africa need support is the monitoring of research projects once they have been approved. One prominent Kenyan ethics committee had only recently carried out its first on-the-spot inspection at the time of fieldwork in November 2005. Prevented by financial constraints from conducting such inspections more frequently, committees in both countries generally rely on reports from investigators and word of mouth. This was described as "passive monitoring" by members of two South African RECs.<sup>227</sup> Another interviewee said that, in general, committees are inadequately funded:

Even though thousands of millions of dollars are spent on research every year, the support that ethics committees receive for their evaluation of research is relatively skimpy. Scholars and professionals are expected to work on those committees in their spare time, as though it's work not worthy of any remuneration. In my view much lip service is paid to ethics, with inadequate commitment to providing the resources required to support the onerous work that needs to be done.<sup>228</sup>

<sup>224</sup> SARETI Newsletter: March 2007; [www.irensa.org](http://www.irensa.org) (accessed 29 August 2007).

<sup>225</sup> Interview with SA\_24.

<sup>226</sup> Interview with K\_09.

<sup>227</sup> Interviews with K\_17, K\_19, K\_25, SA\_10 (quoted), SA\_14, SA\_17 (quoted) and SA\_19.

<sup>228</sup> Interview with SA\_09.

It might be that through the attendance of policy-makers at courses run by SARETI, IRENSA and the newly formed regional bioethics centre in Kenya (see below), the need for increased funding for ethics committees will be recognised. This is also a pertinent issue for the proposed GGI, as any expansion of genetic research in developing countries will have to be matched by increased capacity for ethical review.

As previously mentioned, the Kenya National Commission for UNESCO has established a regional bioethics centre, having recognised that the country did not have the facilities to implement the articles in the UDHGHR (1997) and the IDHGD (2003) concerning ethics education.<sup>229</sup> Having been approved at the 2005 General Conference, the "Regional Centre for Documentation and Research on Bioethics" at Egerton University, Kenya, was inaugurated in May 2007 by the Director-General of UNESCO.<sup>230</sup> The plans for the Centre were welcomed by interviewees from the KEMRI ethics committee and the National Council for Science and Technology, who saw it as a good opportunity for information sharing.<sup>231</sup> The Centre's remit extends beyond research ethics, its ultimate aim being to increase understanding of what bioethics means among as many policy-makers, stakeholders and citizens as possible.<sup>232</sup> In August 2008 it will host a conference on "Bioethical Perspectives and Practices in Research, Medicine, Life Sciences and Related Technologies in sub-Saharan Africa." Thus the Centre, promoted by the UNESCO National Commission and the Bioethics Chair, would appear to represent the kernel of an active community around the declarations in Kenya, of the type that Young has observed in other regimes.

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<sup>229</sup> Interviews with K\_01, K\_13 and K\_16.

<sup>230</sup> UNESCO, "Next session of International Bioethics Committee to be Held in Kenya from 17 to 19 May," [http://portal.unesco.org/en/ev.php-URL\\_ID=37777&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=37777&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 25 May 2007). The draft resolution on the Centre (33 C/DR.53) was approved by the General Conference as an amendment to the Draft Programme and Budget for 2006-2007 (33 C/5). (UNESCO, "Volume 1: Resolutions," Records of the General Conference, 33rd Session, Paris, 3 to 21 October 2005, 33 C/Resolutions (Paris: 2005), 193.)

<sup>231</sup> Interviews with K\_17, K\_19 and K\_20.

<sup>232</sup> Interview with K\_13.



## 6.4 SUMMARY AND CONCLUSIONS

This chapter has shown that, despite the substantial efforts of UNESCO to promote its three declarations on genetics and bioethics and the norms contained therein among policy-makers, experts and the general public, direct uptake by member states (as far as this can be measured) has been poor. This is partly because the declarations are non-binding instruments and thus carry no obligations on sovereign states. It is also because, in some instances, states already have adequate policies in place. In Kenya and South Africa, several of the general ethical principles in the declarations are being implemented almost by default, reflecting their similarities to those contained within instruments such as the *Declaration of Helsinki* and the CIOMS guidelines, on which national level legislation and regulation are often based.

For those states which have not yet established bioethics systems, the declarations may galvanise them into doing so, or at least this is what UNESCO hopes. The example of Kenya and its slow movement towards legislation specifically on human genetic research would indicate that the commitment by governments enshrined in the declarations is not felt to be a particularly pressing one, however. It may be that the added value of the declarations lies more in the capacity building initiatives they have spawned than in the documents themselves. To this end, UNESCO may want to investigate how it could help Kenya, South Africa and perhaps other countries address specific issues in more detail than can be captured within the general principles of the declarations, such as how to engage appropriately with communities, ensure long-term capacity building and effectively monitor research projects.

Member states of UNESCO have shown more interest in the drafting of the declarations than in their implementation, reflecting the compromise attached to non-binding instruments. The proposed GGI seems to be facing a similar problem. Despite TJCB's insistence on urgency, there appears to have been little progress towards forming a

network since its bringing together of “creative minds” in 2004.<sup>233</sup> Thus actual implementation has proved harder and slower than the planning process. A South African interviewee said of the UDHGHR (1997), “I think it would have had more of an impact if it was a convention, but then we’d probably still be in negotiations fifteen years later... So I think it’s probably the best that could be done at the time.”<sup>234</sup> Chapter 7 asks whether, in a world of sovereign states, a more effective governance system for genetics and bioethics might be possible.

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<sup>233</sup> Acharya *et al*, “Better Global Governance to Promote Genomics for Development,” 6.

<sup>234</sup> Interview with SA\_37.



Bioethics and genetics stretch beyond national borders in several ways. Multi-centre research projects are increasingly common and require a coordinated system of ethical review. Tissue samples and genetic data frequently traverse national boundaries. The human genome has been designated the 'heritage of humanity' and should thus be of benefit to all. Inequalities of health are considered a global injustice, perhaps to be partly addressed through closing the 'genomics divide'.<sup>1</sup> Such issues are unlikely to be dealt with effectively at national level only, hence the efforts of UNESCO to provide an international framework for their governance. These efforts, embodied in three declarations on genetics and bioethics, illustrate many of the characteristics commonly witnessed in international institutions, as shown in Chapters 5 and 6. The declarations saw unequal relations between North and South in their negotiation and a lack of input from non-state actors, which has subsequently affected their perceived legitimacy. As far as it can be measured, their implementation at national level, direct or indirect, has been ambivalent at best. This chapter explores whether these problems could be addressed within the UNESCO framework, or whether a new mode of global governance is needed, perhaps in the form of the Global Genomics Initiative. It begins with a brief overview of the approaches to global governance introduced in Chapter 3, before discussing the issues raised in Chapters 5 and 6 on a thematic basis.

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<sup>1</sup> Although a few interviewees thought genetic research could be a distraction from more basic and effective means of addressing inequalities of health (SA\_03, SA\_09 and SA\_20), many more believed such research worth pursuing, because of its long-term potential to produce treatments or cures for the diseases of the South (K\_08, K\_11, K\_25, K\_26, SA\_21, SA\_27, SA\_30 and SA\_32). Two interviewees from South Africa commented that it should not divert resources from meeting basic needs in the here and now, but that the two approaches could be complementary (SA\_37 and SA\_18). Some of the Kenyan participants remarked that the connection between genetics and development, in terms of the opportunity to alleviate poverty through better health, had not been made by the public at large (K\_04, K\_08, K\_14 and K\_25).

## 7.1 THEORY REVISITED

Regime theory provides insights into how and why international agreement is reached on a given issue, within formal or informal settings. States are usually the principal members of international regimes (as for the UNESCO declarations), although other actors are also often involved in both decision-making on norms and their subsequent implementation. Overlapping mandates among organisations are not uncommon, due to the *ad hoc* nature of the international system. Power differentials, between strong and weak states and between state and non-state actors, can affect the outcome of an institution's deliberations. Agreements frequently represent compromise positions rather than coherent policy design and may be couched in ambiguous terms. Where non-binding norms are chosen over binding ones, the standards set may be relatively high but their implementation will be harder to ensure. Suggestions for increasing the efficacy of regimes as instruments of global governance include encouraging greater civil society participation, improving reporting mechanisms and finding more funding for implementation activities.

Global policy networks, government networks and cosmopolitan democracy have been proposed as potential means to improve on current global governance mechanisms such as regimes. Global issues networks (GINs), the brainchild of Jean-François Rischard, would deal with various global problems as single issues. Each network would include representatives from governments, civil society and industry as equal partners, all of whom would act as 'global citizens' to ensure fair decision-making. Broader input would also be sought, through the internet. The main activities of the networks would be the formulation of norms and standards applicable to all stakeholders in the issue at hand and the subsequent 'naming-and-shaming' of those who failed to comply.<sup>2</sup>

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<sup>2</sup> These ideas are articulated most comprehensively in Rischard's book, *High Noon: Twenty Global Problems, Twenty Years to Solve Them*.



Governance through government networks, championed by Anne-Marie Slaughter, would see government officials becoming the prime actors in the international arena. Each would liaise with their counterparts across national borders and in supranational institutions, to effect global governance. Horizontal networks would involve only domestic government officials (although they might be hosted by an international organisation); vertical networks would include officials from supranational institutions to which sovereignty had been delegated. The networks would be formed around particular issues, their memberships comprising relevant governmental departments and units rather than unitary states. Their main aim would be to support and encourage government officials in the performance of their duties, national or international.<sup>3</sup>

Cosmopolitan democracy, as espoused by David Held and Daniele Archibugi, would regulate at global level those issues that extend beyond national borders, within an overarching system of multilayered governance based on the cosmopolitan values of individualism, universalism and impartiality. This system would seek to ensure that all those significantly affected by a given issue had the opportunity to participate in decision-making around it, as members of communities defined by common interest and need rather than geographical boundaries. Human rights would be upheld irrespective of state sovereignty, as a global assembly would embed universal norms and standards and intervene directly should governments or other bodies fail to abide by them.<sup>4</sup>

## **7.2 RELATIONS BETWEEN NORTH AND SOUTH**

The three UNESCO declarations on genetics and bioethics constitute a formal regime, in that they encapsulate norms and principles emanating from the decision-making procedures of an intergovernmental organisation and its member states. Drawing on the

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<sup>3</sup> See Slaughter's book, *A New World Order*.

<sup>4</sup> See, *inter alia*, *Global Covenant* by Held and "Cosmopolitan Democracy and its Critics: A Review" by Archibugi.

work of UNDP on global public goods, Held argues that relations between states are often unequal in such regimes, despite formal parity, because developed countries are able to send larger and more expert delegations to meetings than are developing ones.<sup>5</sup> This was indeed the case during the negotiations for the UNESCO declarations. Although procedures were followed scrupulously in terms of giving all countries equal voice and vote, delegates from the North were both more numerous and more experienced than those from the South (see 5.1.1.2). Participation programmes, issue-based networks, government networks and cosmopolitan democracy have all been put forward as means to address such failings in the current international system. Might they enable developing countries to attain true parity with developed ones, within or without intergovernmental organisations (IGOs)?

Held's blueprints for cosmopolitan democracy include new or existing regional governance structures, the decisions of which would be "recognized and accepted as legitimate independent sources of regional and international regulation."<sup>6</sup> The negotiations for the UDBHR (2005) demonstrated how collaborations within and between regions of the South afforded them a platform from which to demand an article on social responsibility (see 5.1.1.2). These collaborations formed around a special issue, as recommended by Chasek and Rajamani in the UNDP study, but maintained the power of a broad coalition. This is perhaps why they were successful, although this came at the expense of some national interests, as in the case of Kenya. Had these groupings had the backing of, say, legitimised regional parliaments, their position might have been even stronger. In turn, they might also have faced stiffer opposition from the European countries, had these presented a united front through the European Union or Council of Europe.

On another tack, regional bodies could host international deliberations on a rotational basis. UNESCO's International Bioethics Committee has already adopted a similar practice, regularly holding sessions outside Paris headquarters (as in May 2007, when it

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<sup>5</sup> Held, *Global Covenant*, 95-96.

<sup>6</sup> *Ibid*, 112.



met in Nairobi, Kenya); perhaps this could be extended to include formal negotiations.

This would seem fairer than the system employed for the drafting of the three UNESCO declarations, whereby representatives from poorer countries generally had to travel further and therefore at greater expense than their developed country counterparts in order to attend negotiations. An alternative would be to help low income countries meet the travel costs of their delegations, perhaps through a participation fund as suggested by UNDP (see 3.5.2), but an organisation like UNESCO would require a substantial injection of funding to be able to offer such assistance. Moreover, neither subsidised travel nor rotating venues would address the problem of unequal levels of expertise among states, although UNESCO's capacity building programmes might do (see 6.2.1).

Rischarde posits that IGOs, with their "global membership," could facilitate the recruitment of representatives from developing countries as members of nascent networks, who might otherwise be left out.<sup>7</sup> Might the proposed GGI call on UNESCO to help bolster its planned southern base, which some interviewees saw as key to its legitimacy (see 5.1.5.1)?<sup>8</sup> UNESCO does have a reasonable record of working with developing countries and listening to their perspectives, as manifested in the evolution of the social responsibility article. The problem, however, is that it cannot guarantee how far those at the negotiating table actually represent their constituents. As revealed by the fieldwork data, there are many people in Kenya and South Africa across the sectors from which TJCB anticipates recruiting members—government, industry, civil society and academia—who had neither heard of the declarations nor been involved in their drafting. Thus the GGI could not rely on UNESCO to engage leaders from the South; rather it would need to reach those at national level whom its formal counterpart has not. These findings have broader implications, too, in that Rischarde may have attached too much importance to IGOs as membership facilitators in his GIN proposals.

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<sup>7</sup> Rischarde, *High Noon*, 189.

<sup>8</sup> Reinicke avers that it is essential that representatives from the developing world be included in global policy networks: "The mere façade of inclusiveness may prove their fatal weakness... The inclusion of less powerful yet important groups from the developing world is critical not just for designing policies but even more so for implementing them." (Reinicke, "The Other World Wide Web," 55-56.)

Slaughter acknowledges a criticism sometimes levelled at existing government networks: that their lack of “representation rules, voting rules, and elaborate negotiating procedures” can result in the deliberate exclusion of weak states.<sup>9</sup> Although the formal procedures of IGOs cannot guarantee equality among states, they do offer some form of protection to the interests of weaker members. Is this something TJCB should consider if it is to ensure the proposed GGI is southern-led? As it is hoping to avoid such procedures, deeming them unnecessarily bureaucratic and unwieldy, its challenge is to find alternative safeguards. Slaughter’s recommendations in this regard (broader policy networks, greater visibility and so on; see 3.5.1) do not seem to deal with the fundamental problem of differences in negotiating power between states. More pertinent is her suggested meta-level norm of ‘global deliberative equality’, under which any government official who met specific criteria would be entitled to join a given network and to listen and be heard within it. Capacity building programmes (similar perhaps to those of UNESCO) would help those from poorer states meet these criteria.<sup>10</sup> It is open to doubt whether this norm, particularly without the backing of formal rules, would suffice to ensure southern voices in the GGI received their due attention, however (see also 7.5).<sup>11</sup>

### **7.3 RELATIVE INFLUENCE OF STATE AND NON-STATE ACTORS**

Non-state actors played a part in the various drafting stages of the UNESCO declarations, through written and verbal consultations, but it was government representatives who made the final decisions, as would be expected in a state-centric regime. At national level, as premised in the previous section, many of those in Kenya and South Africa who might be considered experts in genetics or bioethics were not asked to feed into their country’s

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<sup>9</sup> Slaughter, *A New World Order*, 28.

<sup>10</sup> *Ibid*, 247 and 259.

<sup>11</sup> Antonio Franceschet has commented that the foundational norm of ‘global deliberative equality’ may not be strong enough to address global inequality, poverty and power imbalance. Nor does he see capacity building and sharing of best practices as sufficient to “confront the implications of current power asymmetries among states and societies.” Hence his assessment that Slaughter’s book “tends to reinforce a model of global governance that is heavily stacked in favor of the powerful and privileged.” (Franceschet, “A New World Order,” 530.)



negotiating position, let alone to join a delegation. The problem for these states, then, seems to have lain in their incapability (financial or otherwise) to harness expertise, as much as a lack of expertise *per se*. This is noteworthy, because if the declarations are adopted at national level as intended, it will be the scientists and ethicists in both the public and private sectors who will be primarily responsible for applying the resultant laws, regulations or policies in their everyday pursuits. Their input might have helped to ensure workable norms, as per Victor *et al*'s observations about 'implementation expertise' during negotiations facilitating better agreements. It might also have triggered the formation of a community committed to fostering the declarations, an important element in the success of regimes according to Young. The wariness of scientists in Kenya and South Africa of becoming involved in policy endeavours corroborates Victor *et al*'s analysis that this does not always follow, however.

Slaughter uses a similar argument in favour of government networks: agreements within these networks would be directly implemented by those government officials who had negotiated them.<sup>12</sup> For this to work, the officials would have to be government employees from a relevant department or ministry, rather than diplomatic attachés or persons from other sectors appointed to represent their governments on a one-off basis, as was often the case at meetings on the UNESCO declarations.<sup>13</sup> Slaughter sees government officials as prime repositories of expertise:

What better source on how to run a securities system, regulate commercial banks, protect the environment, pursue different types of criminals, safeguard human rights or foster business competition than networks of government officials from around the world charged with precisely those functions?<sup>14</sup>

Were such officials to be selected for the proposed GGI, might its norms fair better than UNESCO's? In terms of adoption into national systems, the answer would likely be yes, given the lack of knowledge and subsequent implementation of the declarations by members of, for example, South Africa's Department of Science and Technology (see

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<sup>12</sup> Slaughter, *op cit*, 263.

<sup>13</sup> See, for example, the lists of participants attending intergovernmental meetings of experts aimed at finalising the IDHGD (2003) and UDBHR (2005).

<sup>14</sup> Slaughter, *op cit*, 178.

5.2.2). In terms of legitimacy, however, this would depend on whether the officials were indeed considered the best sources on how to regulate genetics and bioethics by those likely to be affected by the norms, or had at least sought their advice. Thus the GGI, to garner legitimacy through being underpinned by states as planned, would have to ensure its government members appeared both competent and accessible. As Chapters 5 and 6 illustrated, the legitimacy and accountability of governments' international activities are not inherent, but are compromised by long or broken chains of delegation and communication, running within and between different departments and ministries and from the executive to the populace. These problems cast doubts on Slaughter's assumption that her new world order of governance through government networks would ensure "bottom up" decision-making, with constituents able to hold officials to account for their actions at both national and global levels. Slaughter acknowledges that government networks in their present format are not always particularly visible and makes several suggestions as to how this might be improved, including greater interaction with other sectors.<sup>15</sup>

How far other sectors should play a role in global decision-making lies at the crux of the different approaches to global governance under discussion. In a world order of government networks, all those affected by an issue would have a right to participate, but this would be through government representatives. Thus governance through government networks would resemble state-centric regimes, in that ultimate decisions would lie in the hands of government officials, albeit often those more closely connected with the issue at hand than many of those who attend IGO deliberations. Slaughter's suggestion that these networks should engage systematically with their counterparts in the corporate and civil society sectors would help them to avoid some of the problems UNESCO has encountered in terms of visibility, especially if this was expanded to include scientists and ethicists (specifically with regard to genetics and bioethics), as per the proposed GGI.<sup>16</sup> In essence, however, the hierarchy between state and non-state actors would not be

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<sup>15</sup> Ibid, 28-29 and 257.

<sup>16</sup> Ibid, 225.



diminished and thus could be a source of tension, as it has been in UNESCO at both international and national levels (see 5.1.3 and 5.2.2). By contrast, regimes as public spheres, issue-based networks and cosmopolitan democracy have been put forward as possible means to encourage not just a greater but also a more equal involvement of non-state actors than is seen in traditional governance mechanisms. This in turn carries potential complications. How can everyone be included in the decision-making process without it becoming unwieldy?<sup>17</sup> If the people to be included are restricted to only those with a legitimate claim to a stake in a given issue, how is this to be adjudicated?

According to Samhat, international institutions have already opened their deliberations to non-state actors to a significant degree, directly and through documentation. UNESCO has ostensibly done both, most of its meetings being held in public and recorded in the public domain, but many stakeholders in genetics and bioethics in Kenya and South Africa remained unaware of the organisation's activities in their field. Issue-based networks, such as those elaborated by Rischard, would be expected to improve on the representativeness of IGOs, by involving government, corporate and civil society actors in an equal partnership. With the addition of academics,<sup>18</sup> the plans for the GGI were originally based on this model. This proved popular with several interviewees in Kenya and South Africa, who saw inclusion of different sectors as a source of legitimacy. As in GINs, membership would be based on knowledge and expertise, a favourable option given the importance that having the 'right' people involved in an initiative appears to bear (see 5.1.5.3). How this expertise would be assessed and selected thus becomes a pertinent question. In 2004 TJCB claimed to be bringing together "some of the best

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<sup>17</sup> This has been identified as a problem in some existing global policy networks: "Although the degree of inclusion of stakeholders is critical to a network's legitimacy, large numbers of participants may result in sizable, sometimes prohibitive, transaction costs." (Benner, Reinicke and Witte, "Global Public Policy Networks," 21.)

<sup>18</sup> While Rischard claims that GINs would be non-hierarchical, he recommends that they should have separate advisory panels of scientists. This separation would be in order to maintain scientific independence, but in reality would re-create the two-tier system seen in UNESCO, whereby the committee of experts, the International Bioethics Committee, is not involved in final decision-making. It seems strange to treat scientists differently from other non-state actors, namely private sector and civil society representatives, rather than expect them, like the other groups, to act as 'global citizens' (see 7.4). The GGI proposals do include academics among the network membership (except in the final 2006 publication). The data in this thesis would suggest that scientists should be incorporated into the GGI (if established) as full-blown members, as they have "hands-on" experience that others lack and would be intimately involved in enacting the network's norms and activities.

creative minds” from the various sectors, to set the agenda and goals of the fledgling network.<sup>19</sup> Held’s criticism of Rischard’s GIN model—that it fails to clarify how the range of people to be involved would be decided—could also be levelled at TJCB, as it has not articulated on what grounds these creative minds were being chosen.<sup>20</sup> Rischard claims that because GINs would not enact legislation (and thus not act like a state), issues of democratic representation would lose their cogency.<sup>21</sup> Representation becomes, if anything, a more cogent issue in such networks, however; the *raison d’être* of the GGI, for example, would lie in its being more truly representative of a diverse range of stakeholders than traditional IGOs.

Some of those interviewed in Kenya and South Africa were concerned not only that bioethics and genetics experts had not had input into the draft UNESCO declarations, but also that those who might be affected by their provisions, such as potentially vulnerable research subjects, had not been consulted either (see 5.1.2.2). Regimes as public spheres, issue-based networks and cosmopolitan democracy provide different solutions as to how broader participation can be ensured fairly and effectively. GINs would be open to “all interested parties,” but the size of these potentially vast constituencies would be mitigated by each GIN addressing a sharply delineated problem.<sup>22</sup> Regimes, under Samhat and Ellis’ schemata, would be similarly framed to include all those affected by a specific issue, through the conduit of civil society organisations. For cross-cutting issues like genetics and bioethics, specificity could prove problematic, as related problems or root causes might not get dealt with. In terms of closing the ‘genomics divide’, for example, even if vaccines against endemic diseases were to be discovered as a result of technological capacity building in developing countries, these might have little impact if the health infrastructure necessary for their administration did not improve in tandem. Thus

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<sup>19</sup> Acharya *et al*, “Better Global Governance to Promote Genomics for Development,” 6; Acharya *et al*, *Genomics and Global Health*, 43-44.

<sup>20</sup> Held, *Global Covenant*, 107.

<sup>21</sup> Rischard, *op cit*, 188.

<sup>22</sup> *Ibid*, 170 and 174.



Rischarde's suggestion of a twenty-first GIN for coordination purposes would be imperative to the efficacy of his model as a means to solving global problems.<sup>23</sup>

Cosmopolitan democracy takes an alternative approach to the inclusion of all interested parties, as only those significantly affected by a given issue (in terms of life chances and expectancy) would be invited to participate in decision-making around it, as a 'community of fate'.<sup>24</sup> Without sharp delineations between issues, however, determining who falls within this category for genetics and bioethics could prove difficult, given that the UDHGHR (1997) declares the human genome the 'heritage of humanity' and TJCB labels genomics a 'global public good'. Speculatively, genetic and biomedical research has the potential to affect the life expectancy and life chances of everyone on the planet. Furthermore, Held's critique of GINs, outlined above, could equally be applied to his model of cosmopolitan democracy, as he does not make clear who would set the 'significantly affected' criteria, or who would arbitrate whether people had met them. The GGI, if established, would have to address such issues, as one of its aims would be to encourage equitable participation, from concerned citizens as well as the various stakeholders: "The GGI would represent a dedicated effort to hear *all voices* in the genomics debate. Participation rooted in the *right to be involved* would be essential for building consensus and avoiding knee-jerk reactions to the technology"<sup>25</sup> (italics added). In short, how and by whom the "right to be involved" should be adjudicated would need to be determined.

Rischarde and Held suggest possible mechanisms through which the voices of those interested in or significantly affected by a given issue could be heard. During the 'norm-producing phase', GINs would be broadened beyond the multisectoral partnerships into a "virtual public space" (through 'electronic town meetings' or ETMs), with the intention of

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<sup>23</sup> Ibid, 190-191.

<sup>24</sup> Held, *Global Covenant*, 98-100 and 107.

<sup>25</sup> Dowdeswell et al, "Realising the Promise of Genomics," 138; Acharya et al, *Genomics and Global Health*, 43.

shortening the distance between decision-makers and the general public.<sup>26</sup> The precedent set by UNESCO is not encouraging in this regard. Despite the drafting process for the UDBHR (2005) being open to “the greatest possible number” through the UNESCO website,<sup>27</sup> there appear to have been significant gaps between decision-makers and stakeholders even (ethicists, scientists and those from government departments not directly connected with the organisation), let alone the wider public. Moreover, ETMs might be biased towards the North, given the internet access problems of some people in developing countries (see 6.2.1).

Cosmopolitan democracy would comprise “an overarching network of democratic public fora,” from the local to the global, through which people could engage in decision-making, either directly or indirectly. The fora would include diverse public spheres (see 7.5) and general referenda at regional or global levels. The latter would not poll everyone, but rather only those considered to be significantly affected by the issue at hand; a cross-section of society; national policy-makers and legislators; or a combination of these groups.<sup>28</sup> Held does not say how or by whom the referenda would be conducted. If they were to be internet-based they might face the same problems as ETMs; if responsibility fell to IGOs like UNESCO these would require increased budgets to be able to run such activities efficiently on a grand scale.

Chapter 5 highlighted two elements that would be key to global polling through either ETMs or general referenda being carried out successfully. The first would be a good marketing strategy, the second sufficient incentive to take part. People would need to be aware of their opportunities for input and to believe that the initiative providing them had the wherewithal to make a real difference. In this sense, those interested or significantly affected would be self-selecting. At the partnership as well as the broader level, there is an assumption on the part of Rischard and Held as authors and the TJCB team as would-

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<sup>26</sup> Rischard, *op cit*, 174 and 182.

<sup>27</sup> UNESCO, “Report by the Director-General on the Drawing up of a Declaration on Universal Norms for Bioethics,” 1 and 7. (See also Chapter 5, note 77.)

<sup>28</sup> Held, *Global Covenant*, 113.



be practitioners that those outside government have the time and inclination to become involved in governance. The quick dissolution of the Africa Genome Policy Forum provides an example of how difficult it can be to maintain an initiative, even among stakeholders in a given issue (see 5.2.3). As mentioned above, scientists in particular are often cautious of committing themselves to pursuits outside their core research and teaching activities, their apparent enthusiasm for a GGI-like network notwithstanding.

#### **7.4 OVERLAP BETWEEN GOVERNANCE MECHANISMS**

The proposed GGI, in order to make a real difference, would have to offer something existing global initiatives in genetics and bioethics do not, or else it would simply perpetuate a common problem in the international system, that of overlapping mandates among different bodies. Its proposed aims are in fact very similar to those of UNESCO's Bioethics Programme, in terms of capacity building, knowledge sharing and public engagement. Worse, it would also seek to produce definitive ethical norms for "genomic technology research."<sup>29</sup> Given the seeming lack of communication between TJCB and UNESCO, this produces an arena ripe for the duplication of activities and purportedly universal standards (see 6.1.2 and 6.2.2). Perhaps to mitigate such worries, in its final publication on the GGI (2006), TJCB recognised the continuing significance of IGOs.<sup>30</sup> Do the networked governance or cosmopolitan democracy approaches offer any means by which the GGI could add to UNESCO's efforts without encroaching on them?

Networked governance, as espoused by Rischard and Slaughter, would see issue-based or government networks working with IGOs, to a certain degree. To address urgent global problems with the requisite alacrity, GINs would have to capitalise on the resources and experience residing in existing institutions. Rischard envisages IGOs facilitating the membership selection process (as described above) and funding the implementation of

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<sup>29</sup> Dowdeswell *et al*, *op cit*, 138.

<sup>30</sup> *Ibid*.

any recommendations the GINs might make.<sup>31</sup> Whether this is realistic is debatable, given that IGOs often lack sufficient backing for their own activities. As shown in Chapter 6, for instance, UNESCO's pool of funding under the Bioethics Programme is limited, thus it seems unlikely it would be able to support the GGI financially. Rather, the GGI might be in a position to assist UNESCO, if it succeeded in securing "alternative financing options" as per its aims.<sup>32</sup> These alternative funders would in all likelihood be based in the North, thus they would have to act as 'global citizens' (see 7.5) in order for the goal of a southern-led network to remain uncompromised.<sup>33</sup> Another suggestion that Rischard makes with regard to IGOs—which it might be pertinent for the proposed GGI to follow, given the proliferation of norms around genetics and bioethics—is that GINs could encourage compliance with existing treaties (or perhaps declarations), "if some useful ones are to hand."<sup>34</sup> If the UNESCO declarations are indeed considered to be of some use, if the GGI was to promote the norms contained therein rather than formulate its own, this might render the relationship between the two initiatives one of cohesion rather than confusion.

In the international system as it operates now, IGOs can generate government networks or vice versa, according to Slaughter. Treaties and agreements trigger the formation of government networks as an "inevitable part" of their implementation, or IGOs evolve in support of horizontal government networks (that is, networks of national officials).<sup>35</sup> In the new world order Slaughter envisages, IGOs would play something of a secondary role within horizontal networks (vertical networks, which would grant IGOs greater power, are discussed in 7.6):

Imagine a global governance system principally composed of horizontal government networks of counterpart national officials, working on their own behalf or to implement formal international obligations... Many, if not most, of the international organizations dotting this landscape, regardless of form or title, are in substance largely facilitative "information agencies"; their job is to collect, distill,

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<sup>31</sup> Rischard, *op cit*, 170, 172 and 185.

<sup>32</sup> Dowdeswell *et al*, *op cit*, 138.

<sup>33</sup> Reinicke notes that governments or IGOs often provide the seed money to set up a global policy network, but that in the long term funding from various sources is necessary to facilitate consensus building and preserve credibility. (Reinicke, *op cit*, 55.)

<sup>34</sup> Rischard, *op cit*, 176.

<sup>35</sup> Slaughter, *op cit*, 153.



and disseminate information needed by network participants and to help the networks coordinate their work.<sup>36</sup>

Both Rischard and Slaughter, then, see IGOs playing a chiefly facilitative role relative to their networks. With regard to UNESCO and the proposed GGI, if UNESCO was to act as facilitator, where would this leave the GGI in terms of being overall coordinator of a “network of networks”?<sup>37</sup> UNESCO, like other IGOs, conducts many activities beyond simply information collection and dissemination, such as the Ethics Education Programme (see 6.2.1). There would appear to be no valid reason why it or its sister agencies should drop such activities, if they are meeting a need. It may be, however, that UNESCO could draw on the government network framework to promote stronger implementation of its declarations among member states. Government officials came together to draft the three declarations, but there have been no equivalent gatherings to discuss how well or otherwise these are being implemented now they have been adopted. A network of government officials formed around the declarations might induce greater peer pressure on states to adopt the said instruments, while at the same time providing them with a source of mutual support to do so (7.6 discusses the soft power of horizontal networks further). Perhaps the GGI could provide the required space and incentive for networking between states, especially if it took on the norms promulgated in the UNESCO declarations rather than drawing up its own.

Should the GGI be formed not as a single entity but as one of Rischard’s twenty GINs or part of Slaughter’s lattice of countless government networks, there would be room for duplication within these frameworks as well as between them and more traditional IGOs. As shown in the previous section, Rischard’s twenty-first GIN would be necessary to prevent overlap between GINs addressing specific but cross-cutting issues such as poverty, infectious disease and migration (three of his twenty problems<sup>38</sup>). If there were

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<sup>36</sup> Ibid, 164-165.

<sup>37</sup> Dowdeswell *et al*, op cit, 138.

<sup>38</sup> Rischard, op cit, 66.

myriad government networks addressing these types of issues, officials might consider it an inefficient use of their limited time to become involved in more than a few of them.

Held's "overarching network of democratic public fora" might face similar problems. Traditional IGOs would have a place in cosmopolitan democracy, among a wide range of other decision-making bodies, from the local to the global.<sup>39</sup> (Those with social mandates would be particularly welcome, a qualification that UNESCO meets by virtue of the UDBHR's social responsibility article.) Without some overall coordination mechanism, such as a global government, would there not be a danger of the confusion of responsibility Held has identified in the current international system simply being perpetuated? By way of example, an 'array of fora'<sup>40</sup> for genetics and bioethics governance is emerging, comprising UNESCO and the proposed GGI (along with other international organisations such as WHO, HUGO, the World Medical Association and CIOMS), regional bodies such as NEPAD and national and local ethics committees and community engagement mechanisms. The resulting proliferation of ethical guidelines at all levels has proved confusing for some practitioners, although a perceived need to comply with international standards as laid out in the *Declaration of Helsinki* and the CIOMS guidelines has provided a catalyst for the strengthening of national systems in Kenya and South Africa. UNESCO has attempted to mitigate the overlap at international level by establishing the UN Inter-Agency Committee on Bioethics (see 6.2.2). As this committee is open to non-UN bodies, it may be a forum through which UNESCO, the proposed GGI and other organisations could coordinate their programmes and thus provide mutual reinforcement, in line with Young's positive views on different institutions having similar mandates.

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<sup>39</sup> Held, *Global Covenant*, 109 and 112.

<sup>40</sup> *Ibid*, 115.



## 7.5 DECISION-MAKING PROCEDURES

The GGI might distinguish itself from existing genetics and bioethics initiatives if it could avoid the 'lowest common denominator' phenomenon that afflicts many international regimes. Agreement on the UNESCO declarations' universal principles, for example, was only possible for uncontroversial issues and then only within a general and non-binding format. For the UDBHR (2005), decisions on difficult issues such as stem cell research were postponed until a change in the international political climate should render agreement possible (see 6.1.1). TJCB envisages the GGI having greater success, placing high hopes in the proposed network's capacity for consensus building:

Imagine a collaborative and inclusive network of industry leaders, academics, concerned citizens, representatives from non-governmental organizations (NGOs), and governmental officials, with particular emphasis on developing world representation. Imagine such a network sharing information globally and across sectors, facilitating informed decision-making that would help close the imminent genomic divide. It would provide a common forum for these players to discuss their goals and needs, and create an environment where consensus could be built to address policy needs.<sup>41</sup>

It is hard to imagine, however, that a network encompassing diverse interests and priorities could reach a higher quality consensus—in terms of less compromised, more effective decisions—than UNESCO has managed with its more circumscribed membership, particularly within a quicker timeframe. TJCB puts great faith in the GGI's proposed informal structure in this regard, which it believes would render the network neutral, flexible, agile, unbureaucratic and non-hierarchical. In assuming that this "loose collaboration" would yield inclusivity and so allow poor states to take a lead role (perhaps under a norm akin to Slaughter's 'global deliberative equality'), it ignores the potential for power differentials to come to the fore when not constrained by procedural formalities.<sup>42</sup>

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<sup>41</sup> Dowdeswell, Daar and Singer, "Getting Governance into Genomics," 497.

<sup>42</sup> Dowdeswell *et al*, *op cit*, 139-140. Benner, Reinicke and Witte see the need to reach consensus within global public policy networks as potentially leading to "lowest common denominator" rather than high quality policy outcomes. At the same time, they advocate informality and an insistence on consensus as a means to give weak actors a voice, in the form of "decision blockades and veto positions." (Benner, Reinicke and Witte, *op cit*, 21.) This seems a rather negative solution to unequal power relations. If the GGI adopted this method it would rarely reach a decision, particularly within the fast timeframe demanded. Reinicke, in an earlier paper, highlighted the time-consuming nature of this type of deliberation: "The value of a consensus-building network rests not on its ability to offer quick solutions, but on its creation of an environment that enables parties in conflict to reach an eventual agreement." (Reinicke, *op cit*, 47.)

Furthermore, the plans are lacking in detail. TJCB gives no indication of how often or by what means the GGI would meet. If it is to be a virtual network, some actors in the South may struggle to discharge fully their designated leadership role, due to indifferent internet access.

Do the different governance models carry recommendations on how the high quality consensus sought from the proposed GGI might be attained? Regimes as public spheres and GINs would have multisectoral memberships and thus could generate the same doubt as that levelled at the GGI concerning the potential to propagate consensus. Within GINs, Rischard proposes that each sectoral representative, on pain of expulsion under a 'code of conduct', should have to act as a 'global citizen' rather than defend their own interests. To this end, a GIN would make a constant appeal to specific, universal values that "are a prerequisite to the solution of the global issue at hand."<sup>43</sup> Unfortunately, Rischard does not articulate how these values would be decided upon, but instead seems to assume they exist *a priori*. As the UNESCO declarations exemplify, what constitutes a universal value is contested and unlikely to be specific. Hence a GIN's discussions, if to be dictated by such values, could not proceed with urgency if these first had to be negotiated and agreed upon.

Like Samhat and Ellis, Held uses the concept of the public sphere. He suggests that a cosmopolitan polity could embrace an ethos similar to that of global citizenship, in order to arrive at collective judgements. A diverse range of public spheres would enable informed participation and deliberation, guided by the 'test of impartiality'. Held writes, "Being impartial here means being open to, reasoning from, and assessing all points of view (especially those of people in urgent need); it does not mean simply following the precepts of self-interest."<sup>44</sup> Whether the test was being appropriately applied would be judged according to various conditions, such as freedom from the possibility of one member imposing on another and the acceptability of outcomes to all, irrespective of present or

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<sup>43</sup> Rischard, *op cit*, 174.

<sup>44</sup> Held, "From Executive to Cosmopolitan Multilateralism," 176.



future social positions.<sup>45</sup> These criteria could perhaps be usefully employed by the GGI in its pursuit of consensus. In reality, however, impartial and informed participation is difficult to guarantee, particularly among the broader public, whom the GGI would seek to engage. This has been the case in Kenya and South Africa, where those who might be significantly affected by decisions in genetics and bioethics (in vulnerable communities, for example) have little knowledge of these subjects. To address this, South Africa's Public Understanding of Biotechnology programme aims to inform citizens about biotechnology, so that they can participate in policy-making in this area. The programme tries to be neutral in the information that it gives, highlighting arguments both for and against biotechnology. Finding the right balance has proved difficult, particularly in terms of assessing how best to offset what might be biased information given out by interest groups.<sup>46</sup> Moreover, the deeper question remains, who is qualified to judge what is balanced information?

Slaughter takes a different tack to Rischard and Held, submitting that variations in values could be accommodated in a global governance framework under the principle of 'legitimate difference', which "enshrines pluralism."<sup>47</sup> TJCB appears to have taken this 'constitutional norm' on board, along with that of subsidiarity, as in its latest publication on the GGI it suggests that the proposed network should ensure states are given the opportunity to "prioritise their own health goals."<sup>48</sup> In an area such as genetics, where research projects are increasingly conducted transnationally, the application of these principles could prove difficult. At a more practical level, Slaughter advocates discussion and argument, developed in a positive, trust building manner over time, as a means to achieve "reasoned consensus." These developments are more likely, she says, in

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<sup>45</sup> Held, *Global Covenant*, 109-110.

<sup>46</sup> Interviews with SA\_27 and SA\_29. The Kenya-based African Biotechnology Stakeholders Forum has a similar mandate (interview with K\_10), although its name would suggest otherwise.

<sup>47</sup> Slaughter, *op cit*, 249. Legitimate difference, global deliberative equality and subsidiarity are three of the five 'constitutional norms' that Slaughter suggests could direct how members of government networks should treat each other. She writes, "At the loftiest level, these principles could be understood as part of a global transgovernmental constitution—overarching values to steer the operation of government networks." It seems rather inconsistent on her part to promote "overarching values" while at the same time endorsing pluralism. Would a country be able to opt out of parts of the transgovernmental constitution under the principle of legitimate difference? Perhaps Slaughter views her constitutional norms to be of a sufficiently universal nature that no divergence from them would be legitimate. (*Ibid*, 260.)

<sup>48</sup> Dowdeswell *et al*, *op cit*, 140.

networks where membership is based on common professional standards and ethics, or 'network norms', than in fora characterised by interest-based bargaining, such as regime negotiations.<sup>49</sup> In this respect, informality may be a boon, as illustrated by the following example. During the drafting of the UDBHR in 2005, the chairman, Pablo Sader, arranged an extramural meeting, at which he requested that participants refrain from taking positions and instead engage in open discussion. This helped enable consensus at the subsequent intergovernmental meeting of experts, even on the previously fractious topic of social responsibility.<sup>50</sup> Similarly, a multisectoral membership, while perhaps rendering consensus less likely, would also make it that much more precious. Several interviewees welcomed the proposed GGI as a venue for ripe discussion, precisely because of its anticipated mixed membership (although a few were sceptical, saying that there were enough 'talk-shops' already<sup>51</sup>). This would indicate that broader policy networks, of which government networks would form the backbone, are an important aspect of Slaughter's model.

## 7.6 IMPLEMENTATION AND ENFORCEMENT

Agreements in regime settings are often non-binding, as states are more likely to accede to a document if they know that ultimately they cannot be bound by its contents or sanctioned for not upholding them. The UNESCO declarations fall within this category. Each was adopted "by acclamation" by member states at its designated General Conference (see 2.3.3.1), but subsequent implementation at national level, as far as can be ascertained, has been poor. The relative impunity of states and other actors within the current international system is one of the reasons why networked governance and

<sup>49</sup> Slaughter, op cit, 27 and 203-204.

<sup>50</sup> Chairman Sader also produced a 'non paper' on how outstanding issues might be addressed, which he subsequently distributed to member states. See UNESCO, "Informal meeting with Permanent Delegations Organized by the Chairperson of the Intergovernmental Meeting of Experts (category II) Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics" and the 'non paper' and letters from Mr Sader to the permanent delegations of UNESCO before and after the May meeting, available at: UNESCO, "Different Stages in the Elaboration of the Universal Declaration on Bioethics and Human Rights," [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=3850&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=3850&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed 20 August 2007).

<sup>51</sup> Interviews with SA\_10 and SA\_17.



cosmopolitan democracy have been proffered as alternatives. It is therefore appropriate to ask, would these models derive greater adherence to norms than existing governance mechanisms, if realised? Each would recognise sovereignty, although Slaughter and Held tender new understandings of the concept. Slaughter advocates what she terms 'disaggregated sovereignty', whereby individual government institutions would be responsible for fulfilling international obligations. She also suggests that, for some issues, enforcement power should be ceded to supranational organisations, within vertical government networks.<sup>52</sup> Could this be a solution to UNESCO's difficulties in ensuring that its declarations are implemented effectively? Would governments be more willing to see the declarations become binding conventions if these were to be applied only to particular departments or ministries, the risk of being labelled a pariah in the event of non-adherence thereby being lessened greatly?

Held advocates a qualified sovereignty, to be conferred on those countries that safeguard human rights and democracy, such that states would no longer be "ontologically privileged."<sup>53</sup> The UNESCO declarations are based on universal human rights, as eponymised in two of them, the *Universal Declaration on the Human Genome and Human Rights* and the *Universal Declaration on Bioethics and Human Rights*. Accordingly, they give human rights and dignity precedence over national or cultural considerations. Since they are non-binding, however, they furnish no means to enforce these limitations. Archibugi proffers a vision of cosmopolitan democracy under which coercive power would be shared between government and meta-governmental institutions.<sup>54</sup> Such a brokerage would license UNESCO to enforce its declarations as human rights instruments. The concession of sovereignty would be greater than under Slaughter's proposals, however, as it would be made within a global polity designed to address an integrated security and human rights agenda, rather than a disaggregated vertical network. With regard to genetics and bioethics, it seems unlikely that states would agree to surrender sovereignty

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<sup>52</sup> Slaughter, op cit, 268-269 and 20.

<sup>53</sup> Held, *Global Covenant*, 119 and "From Executive to Cosmopolitan Multilateralism," 168.

<sup>54</sup> Archibugi, "Cosmopolitan Democracy and its Critics," 454.

under any circumstances, disaggregated or otherwise, as evidenced by their reluctance to allow any committal clauses even within the non-binding UNESCO instruments (see 6.1.1.3).

Through its integrated agenda, cosmopolitan democracy might enable broader issues around genetics and bioethics (such as inequalities of health) to be dealt with in a harmonised fashion, which global networks as single issue solutions would struggle to do. Held proposes a direct action assembly, made up of “all states and agencies,” to tackle pressing global problems. He explains, “Its task would be to lay down, in framework-setting law, the standards and institutions required to embed the rule of law, democratic principles, and the minimum conditions for human agency to flourish.” If lower levels of governance could or would not meet these standards and conditions, thus failing to protect people in urgent need, direct intervention would be justified.<sup>55</sup> Non-adherence by one state could potentially affect everyone, given that the assembly would be dealing with global problems. Thus law-abiding states might agree to such a system for the same reason that they sometimes join international regimes: it might be in their rational self-interest to do. Using similar arguments to Benatar (see Chapter 3, note 59), one interviewee articulated why such a long-term view might be necessary, particularly on the part of developed countries:

If the developed world, so-called, doesn't take this challenge [inequalities between North and South] seriously, then there won't be much of a world for any of us. So I don't see it as an option for the developed world to help or aid—in whatever ways practical—the developing world, it's rather a necessity... So until the wealthy in the world realise that it's in their own interest to reach out to the developing world, there won't be the world that we would all like to see.<sup>56</sup>

Another described why a broad approach to genetics and bioethics would be beneficial: “But the solution is not just providing genomics capability, there are much greater issues... So we could have fantastic genomics capabilities in Africa and it would have no meaning

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<sup>55</sup> Held, *Global Covenant*, 110. Held admits that agreement on how the global assembly should be formed and run would be “difficult, to say the least” and would have to be reached through consensus building with stakeholders: “states, IGOs, INGOs, citizen groups and social movements.” (Ibid, 110-111.)

<sup>56</sup> Interview with SA\_18.



to Africa.”<sup>57</sup> This is in direct contrast to TJCB, which has a broad vision to address the inequalities of health that could lead to “social confrontation,” but focuses on advances in genetics as the channel through which to achieve this.<sup>58</sup>

Until such time as states agree to relinquish at a global level a part or the whole of their sovereignty, are there means by which the present system could be rendered more effective in ensuring norm adherence? Victor *et al* advocate systems of implementation review (SIRs) as a means to encourage states to honour their non-binding commitments. Precisely because the declarations are non-binding, however, member states of UNESCO have seen even self-reporting requirements as something of an impertinence. It remains to be seen whether the unofficial collection of implementation data through the Global Ethics Observatory (GEObs) will be more successful, as UNESCO hopes. After the poor response to the evaluation exercise for the UDHGHR (1997), the Bioethics Programme has chosen to concentrate its limited resources on a management approach to effecting implementation. This seems a sensible ploy, given that the various capacity building programmes—GEOBs, Assisting Bioethics Committees and the Ethics Education Programme—were generally well received by interviewees in Kenya and South Africa, with the caveat that they should complement rather than duplicate other initiatives.

Within their issue-based and government network frameworks, Rischard and Slaughter suggest various forms of soft and hard power to encourage implementation. GINs would rely on soft power only, ‘naming-and-shaming’ those failing to meet the standards laid down during the ‘norm-producing phase’. Rischard claims that employing norms in combination with such “reputational effects” would produce results more quickly and effectively than do binding treaties and conventions and the rules and sanctions that go with them.<sup>59</sup> Although TJCB’s publications draw heavily on Rischard’s work, there is no indication within them that the proposed GGI would adopt this mechanism to induce

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<sup>57</sup> Interview with SA\_26.

<sup>58</sup> Dowdeswell *et al*, *op cit*, 140.

<sup>59</sup> Rischard, *op cit*, 170 and 178.

compliance with its norms (indeed how the norms would be enforced is not addressed at all). From the history of the UNESCO declarations, it would seem that there could be no good argument for its doing so, given the emphasis on urgency. The declarations, as sets of non-binding norms, were indeed negotiated in a relatively short timeframe, but their impact in terms of reputational effects may take far longer to come to fruition. Despite being the first bioethics instruments to be adopted by an intergovernmental body, they are usurped in the international arena by longer-standing texts. As an illustration, ethics training programmes in South Africa are more likely to teach the *Declaration of Helsinki* and the CIOMS guidelines than the UNESCO declarations.<sup>60</sup> It will thus take time for the UDBHR (2005), for instance, to become a “normative reference” or a “reference text...for all the stakeholders concerned,” as intended by UNESCO’s Intergovernmental Bioethics Committee (IGBC) and the April 2005 meeting of government experts respectively.<sup>61</sup> This example shows how it could take several years for the naming of an actor as being in breach of GGI or GIN norms to equate to the shaming of their reputation. One interviewee articulated this in a developing country context: “In the West I see that name and shame working, but out here, if people don’t even know what it’s about, then there’s no shame.”<sup>62</sup> Furthermore, it is not only the legitimacy of the norms that must be entrenched, but also that of their purveyors. UNESCO’s claim that it is the organisation best suited to standard-setting in bioethics has been questioned, even though it is an established UN agency. How much more would a newly formed GGI or GIN have to work to ensure its “moral authority”?<sup>63</sup>

Rischar’s ‘naming-and-shaming’ mechanism makes no provision for those actors who desire to reach the required standards, but lack the capacity to do so (apart from the ETMs engaging in best practice exchange<sup>64</sup>). By contrast, Slaughter, like management regime theorists, places great emphasis on capacity, to the extent that “the core

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<sup>60</sup> Interviews with SA\_15 and SA\_16.

<sup>61</sup> UNESCO, “Report of the Third Session of the Intergovernmental Bioethics Committee (IGBC),” 8 and “First Intergovernmental Meeting of Experts: Final Report,” 3.

<sup>62</sup> Interview with K\_18.

<sup>63</sup> Rischar, op cit, 178.

<sup>64</sup> Ibid.



characteristic of sovereignty,” in its disaggregated form, “would shift from autonomy from outside interference to the capacity to participate in transgovernmental networks of all types.”<sup>65</sup> While, like Rischard, she sees prestige as a valuable incentive for states to conform to network norms, she suggests that government networks (horizontal and vertical) could offer willing states technical assistance to meet these norms, rather than name and shame them for not doing so. She classes this type of assistance as hard power, but unlike the more usual sanctions it is of a positive form.<sup>66</sup> Slaughter’s vision appears somewhat blinkered in that she focuses almost entirely on capacity building designed and led by developed countries.<sup>67</sup> As indicated in Chapter 6, the most favourable kind of capacity building is that which is planned in response to local needs, identified by those on the ground (see 6.3.2.3). Relatedly, some interviewees in South Africa said that the North must not impose its norms and practices on the South and should be prepared to see knowledge sharing as a two-way process.<sup>68</sup> Should it be established, the GGI would have to take such messages on board in order to make a real impact in the South and thus fulfil what would be its ultimate aim, to close the ‘genomics divide’.

Horizontal government networks would apply soft as well as hard power, again in positive form, in the form of information provision, socialisation, persuasion and discussion. In the current international system it is in fact UNESCO that is employing these methods in the genetics and bioethics fields, through projects such as GEObs and the “Ethics Around the World” regional conferences (see 6.2.1). Would a network of government institutions be more successful than UNESCO in using soft power to encourage adherence to norms? It might be that government officials could exert peer pressure on their counterparts from other countries more effectively than UNESCO by enhancing the socialisation of norms,

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<sup>65</sup> Slaughter, *op cit*, 34. (See Chapter 3, note 195 for critiques of this stance on sovereignty.)

<sup>66</sup> *Ibid*, 168.

<sup>67</sup> *Ibid*, 19 and 229.

<sup>68</sup> Interviews with SA\_16, SA\_18 and SA\_24. Slaughter does acknowledge that knowledge could flow from South to North, but within an overall framework that hints at condescension: “Where possibilities of genuine learning exist, representatives of even the world’s most powerful nations are likely to be surprised by what they do not know or have not thought of... successful mentoring can often produce students who turn the tables on their teachers.” (*Ibid*, 229-230.)

as Slaughter would suggest (and thus a government network built around the declarations may be a way forward, as discussed in 7.4).<sup>69</sup> In terms of efficiency, however, it would seem sensible to coordinate activities through a central hub. The GEObs database, for example, provides a simple means for government institutions and officials from different states to initiate contact if they so wish, which is surely a better system than them all having to find each other in an *ad hoc* manner. This in effect renders UNESCO a horizontal network host.<sup>70</sup>

One of the forms of information sharing that Slaughter, like Rischard, recommends is the compilation of codes and best practices, which members of government networks could then adapt to local circumstances.<sup>71</sup> Again, this is a function of the GEObs database. What is interesting is that Slaughter advocates pluralism, while UNESCO embraces universalism, yet both have come up with essentially the same methodology for enacting these. This raises the question, how far can universal norms be contextualised before they lose all potency? Or, in other words, at what point do they become plural? Relatedly, Slaughter also endorses “an affirmative norm of friction and constructive ambiguity.”<sup>72</sup> Chapters 5 and 6 demonstrated that ambiguity is neither affirmative nor constructive in some circumstances, however; at both international and national levels, having to choose between several sets of guidelines or rules promulgated by various disparate bodies can be confusing and counter-productive (although some interviewees found the mix of perspectives useful).

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<sup>69</sup> Ibid, 3.

<sup>70</sup> It is worth noting that Slaughter and UNESCO have a slightly different take on the soft power of a tool such as GEObs. Slaughter predicts that one of the merits of a network having a common website in order to make it more visible would be that government officials would know that they were under scrutiny. (Ibid, 237.) For UNESCO, however, one of the advantages of the GEObs database is that it can collect information about how states are implementing its declarations without appearing to be officially monitoring them (see 6.2.3).

<sup>71</sup> Ibid, 249-250.

<sup>72</sup> Ibid, 254.



## 7.7 NATIONAL LEVEL INEFFICIENCIES

Slaughter, like some regime theorists, criticises the international relations discipline for seeing states as single units in the international arena and thus ignoring what happens at domestic level.<sup>73</sup> Among the governance approaches examined in this chapter, it is issue-based networks that fall most completely into this trap. Although explicitly global, GINs would ultimately rely on states to implement their norms within national legislation (just as the UNESCO declarations do) and Rischard assumes that states would have the capacity to do this. Cosmopolitan democracy does not presume national governance capacity, but does require it. Genetics and bioethics, as global issues, would be subject to the laws and standards laid out by the direct action assembly. In a context such as a research project conducted within a single community or country, however, these laws and standards would be applied at a lower level, under the principle of 'inclusiveness and subsidiarity'<sup>74</sup>; hence Held and Archibugi's model of multilayered democratic governance, comprising accountable, responsive and effective politics at local to global levels.<sup>75</sup> Some states might struggle to meet these requirements, because of national level inefficiencies. The Kenyan bioethics system, for example, suffers from poor communications within and between different government ministries (see 6.3.2.1). Cosmopolitan democracy does not articulate how such problems are to be overcome.<sup>76</sup>

Slaughter recognises that sufficient capacity at national level would be needed to meet the requirements of global governance under her new world order and, what is more, makes concrete suggestions as to how this could be achieved (see 7.6). She does not see states as unitary actors, but rather as disaggregated into separate institutions and

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<sup>73</sup> Ibid, 12-13.

<sup>74</sup> Held, *Global Covenant*, 110-111.

<sup>75</sup> Ibid, 102 and 113; Archibugi, "Principles of Cosmopolitan Democracy," 209.

<sup>76</sup> Various commentators note that cosmopolitan democracy does not pay sufficient attention to national level governance. Scheuerman observes that Held and Archibugi have little to say about how legislation produced by a global assembly would be fleshed out at local and national levels, while Wolf and David Mepham assert that the problems of the developing world are attributable as much to poor governments and economic policies as to transnational influences. (Scheuerman, "Cosmopolitan Democracy and the Rule of Law," 449; Wolf, "The Case for Optimism," 40; Mepham, "The Far Side of Globalisation," 60.)

departments.<sup>77</sup> In Kenya, as indicated above, the government is disaggregated in that communications have been poor between its different ministries working in related areas, namely health, education and science and technology. This makes for an inefficient governance system at national level. It also implies that one of Slaughter's justifications for government networks over the global policy networks tendered by Rischard and others, that within governments it is clear who is exercising power on whose behalf, is not valid in all cases.<sup>78</sup>

As outlined in the previous section, under Slaughter's notion of 'disaggregated sovereignty' government units would have discrete mandates to meet international legal obligations. For issues such as genetics and bioethics, which touch on several themes, it might not be obvious which units should be meeting which obligations. Particularly given Slaughter's advocacy of pluralism, this could result in different government departments applying, in diverse ways, various international standards to the same broad issue. Thus networking at national level between the disaggregated units would be essential, in order to avoid such confusion. Such networking would also enable states to garner input from all relevant departments when deciding upon negotiating positions, as recommended by Chasek and Rajamani and might help IGOs to locate and engage with the right national bodies on a given issue, as Young deems necessary. Slaughter seems to believe this coordination would be straightforward, commenting only briefly, "Regulators of all kinds, from health to education to the environment, would conduct their own foreign relations, subject to some kind of domestic interagency process that accepted this phenomenon but nevertheless attempted to aggregate interests."<sup>79</sup> As the Kenyan case demonstrates, however, the existence or efficacy of such a "domestic interagency process" should not be presumed.

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<sup>77</sup> Slaughter, op cit, 5.

<sup>78</sup> Ibid, 4.

<sup>79</sup> Ibid, 232.



## **7.8 SUMMARY**

This discussion has highlighted the strengths and weaknesses of the regime, networked governance and cosmopolitan democracy approaches to global governance, in specific relation to the UNESCO declarations on genetics and bioethics and the proposed GGI.

The final chapter considers the wider implications of these findings for effective global governance as a means to solving global problems, as well as what the future might hold for the governance of genetics and bioethics.

*We must move towards the democratization of health built upon both altruism and self-interest to empower global citizens with the basic knowledge, the voice and participation in health decision-making, and the norms and institutions that are able to advance the ideal and the praxis of the indivisibility of global health.<sup>1</sup>*

Through the lens of international relations theory, this thesis has examined actual and potential mechanisms for the governance of human genetic and biomedical research at global level, as espoused through ethical norms housed within international institutions. Some commentators, such as those at TJCB, see the fruits of this research as instrumental in addressing inequalities in global health. Others, like Benatar, consider these inequalities to be symptomatic of wider divisions between North and South, which will require a paradigm shift in the way the world is governed if they are to be bridged. This paradigm shift would see members of an informed global public involved in both national and international governance mechanisms to a far greater degree than is currently the case. The thesis has shown that, in the governance of genetics and bioethics, who is involved in decision-making has an impact not only on the content of any regulatory or policy outcomes, but also on whether these are perceived as legitimate. This in turn has a considerable impact on whether they can be implemented effectively. In this chapter the wider implications of these findings for global governance are explored, as are the means by which effective governance of genetics and bioethics might be pursued. The chapter ends with some recommendations for further research.

## **8.1 THEORETICAL IMPLICATIONS**

The three UNESCO declarations on genetics and bioethics are in several respects classic exemplars of a formal international regime. Their negotiation demonstrated unequal power between both developed and developing countries and state and non-state actors.

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<sup>1</sup> Chen and Berlinguer, "Health Inequity in a Globalizing World," 27-28.



Opinions among participants were diverse as to which issues should be addressed and in what manner, such that agreement was only possible at a general level, on mostly uncontroversial aspects of genetics and bioethics. The subsequent implementation of the declarations has been slow and rather piecemeal, as might be expected of non-binding norms. Furthermore, UNESCO's mandate overlaps somewhat with those of other institutions. As the organisation is seen by some as a relative newcomer to bioethics, this could have a detrimental effect on its perceived legitimacy.

At a broader level, these problems are typical of the weaknesses in the international system observed by international relations scholars. They invite the question, how might this situation be improved? Any answer would have to address several points: what power and influence state and non-state actors should have, both expert and lay; how everyone can be included who should be; what the optimum balance is between formality and informality; how duplication can be avoided but complementarity strengthened; how norms can be upheld, particularly should state sovereignty be maintained; and the extent to which those norms should be universal. The proposed solutions examined in this thesis—reformed regimes, issue- and government-based global networks and cosmopolitan democracy—differ in the nature and adequacy of their approaches to these issues, as discussed below. In all this it is important to recognise, however, that any new forms of global governance would not replace older ones but would have to be integrated with them, as the structures and norms of the latter will not disappear. Thus UNESCO and other IGOs will surely have a major role to play in the global governance of the future.

### **8.1.1 Deliberation**

How to include everyone who should be involved in global governance without the system becoming unwieldy is a big challenge. As demonstrated by the UNESCO declarations, when state representatives are given prominence over other stakeholders, tensions can

arise if the former are perceived by the latter to be insufficiently expert in the issue at hand, with ensuing implications for the legitimacy of the endeavour. If non-state actors are to be engaged on an equal footing, however, how is their “right to be involved” (to quote TJCB in reference to its proposed GGI network<sup>2</sup>) to be assessed? Drawing from the example of research ethics, it seems that the nature of expertise is contested, as is who among government, civil society, industry and academia should be a judge of this. Despite this, the general opinion across all these sectors in Kenya and South Africa was that a range of experiences and knowledge are needed in decision-making.

Consensus within a multisectoral environment may perhaps seem more improbable than in an organisation with a more circumscribed membership, but this also makes it that much more precious if achieved. Informal discussions are less likely to descend into interest-based bargaining than formal negotiations. It might be harder for all voices to be heard than within formal settings, however, as rules and procedures do provide a moderate safeguard against unequal power relations (as illustrated by UNESCO). New forms of networked governance would rely on members adhering to principles, such as global citizenship and global deliberative equality, according to a ‘code of conduct’ or ‘constitutional norms’, which in turn would render that membership a largely self-selected group. Similarly, cosmopolitan democracy would apply the ‘test of impartiality’. Such reliance on internal measures would raise questions of external accountability, which the UNESCO declarations demonstrate is difficult to achieve even when sought after; that is, despite the organisation’s efforts to be open and transparent (in effect a public sphere), it is still seen by some actors as quite the opposite. Thus both actual and perceived accountability are important to the efficacy of global governance.

New or revised models of governance, as proposed by Young, Samhat, Ellis, Rischard, Slaughter, Held and Archibugi, among others, all look at some level beyond a limited number of stakeholders contributing to decision-making, to the inclusion of the wider

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<sup>2</sup> Dowdeswell *et al*, “Realising the Promise of Genomics,” 138.



public. If this is considered appropriate, the question becomes—at a practical level—whether it can be achieved, particularly in a world of unequal access to communications technologies. Those most significantly affected by global problems such as inequalities of health are usually the poor and vulnerable, who often have the least access to the means to participate in debate, precisely because they are poor and vulnerable. Garnering their informed participation may also be problematic if, despite being significantly affected by a given issue, they know little about it, other than in experiential terms. Where people are both informed and connected, they may nevertheless fail to become engaged, if opportunities for input are not marketed sufficiently.

### **8.1.2 Coordination**

Connectedness between institutions is important to the efficacy of global governance. If uncoordinated, overlaps in both norms and functions can be unhelpful. A proliferation of purportedly universal norms is confusing for practitioners, as has been the case in bioethics. This is an important consideration for those who would promote 'norm production' as an activity of innovative global governance mechanisms, as new norms are unlikely to have sufficient kudos to supersede existing ones, whatever the nature of the initiative or organisation from which they have emanated. That UNESCO's declarations are unique in bioethics because they are the first to have been agreed by governments does not appear to be as significant a claim as the organisation might hope, for instance. Even if norms produced by a multisectoral initiative were considered to have greater legitimacy, they would still be coming into a crowded arena (hence some interviewees were wary of more 'talk-shops'). The consolidation rather than proliferation of norms would therefore seem important.

Duplication of functions can also be problematic, if one organisation is seen to be encroaching on another's turf. New initiatives must either find a niche in which they can

carry out important activities not undertaken by older organisations, or else coordinate with their predecessors to ensure that programmes are complementary, such that what is different about the new initiative is used in support of the old one. Slaughter's model of networked governance is perhaps more compatible with IGOs than Rischard's in this regard. Although both authors' networks would embrace existing international obligations, a government network built around instruments such as the UNESCO declarations might be expected to be more effective than an issue-based network telling its more traditional counterparts to "get their act together."<sup>3</sup>

Coordination, then, is imperative. This is not only the case between old and new governance systems, but also within them. For single issue regimes and networks, whether state- or government-centred or with a multisectoral membership, should they fail to make connections with counterpart bodies working on related issues, solutions will not be holistic. If a broader approach looks to multilayered governance, as would cosmopolitan democracy, coordination between layers will be equally necessary, to avoid a similar confusion of norms and functions as observed in the present international system. At the global level, the direct action assembly envisaged for cosmopolitan democracy would in effect roll all Rischard's single issue networks into one, with its mandate to address all pressing global problems. What would be lost in terms of speed and expertise would thus be gained in a more comprehensive (and concomitantly more ambitious) approach to problem-solving.

### 8.1.3 Implementation

The direct action assembly would require states to potentially relinquish their sovereignty, in that it would be sanctioned to intervene in the event of non-adherence to its framework laws. Such an arrangement seems unlikely to be realised in the current international

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<sup>3</sup> Rischard, *High Noon*, 176-177.



political climate. Krasner stated in 1983, "Of all the actors in the system, states are the least likely to be swayed by appeals to transcend sovereignty."<sup>4</sup> This still rings true today, at least with regard to genetics and bioethics. The alternatives to dispensing with sovereignty are to encourage adherence to norms through hard and soft forms of power. It would seem that positive management is more effective than negative enforcement in this respect, or at least that negative power needs to be backed up with capacity building if it is actually to provoke change in those states that are willing but unable to comply with norms. Building up both reputational effects and capacity for implementation takes time, thus these forms of power need space to develop, the urgency of some global issues notwithstanding.

Whether states have the capacity to implement norms lies partly in the efficiency of national governments. Slaughter's 'disaggregated state' is a useful conceptual tool, as it allows for an unpeeling of the national layer, which is too often ignored in international relations theory. At the practical level, however, governments need to respond to global problems in an integrated rather than disaggregated manner, particularly those problems that are cross-cutting (which most are). Like regimes, government and issue-based global networks and cosmopolitan democracy would all rely on competent governance at the national level to be effective. This would require capacity and coordination, within and between not only government departments but also those actors in academia, civil society and the private sector responsible for applying a given set of norms in their everyday lives. Absent such coordination and the national level simply mirrors the overlapping mandates seen among initiatives at international level, as illustrated by Kenya and South Africa.

The thesis has touched on the issue of universalism versus pluralism, but in doing so has prompted more questions than conclusions. Firstly, how far can the process of contextualisation be taken before 'universal' norms become pluralised? Even where an efficient national system can be assumed, if internationally agreed norms are to be

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<sup>4</sup> Krasner, "Regimes and the Limits of Realism," 367.

effective at this level they must be couched in general terms that leave sufficient room for interpretation, so that different social and cultural traditions can be accommodated. The UNESCO declarations on genetics and bioethics are a case in point. Should their adaptability be regarded positively, as the means by which intergovernmental consensus became possible, or negatively, as a dilution of their norms' potential potency? Secondly, to what extent are definitive norms even desirable? As highlighted above, a proliferation of norms can be confusing for practitioners, thus consolidation would seem a rational path to follow. Some people prefer to have different sets of norms to draw on and amalgamate, however, in order to determine the most appropriate response to whatever matter they happen to be grappling with. In turn, the notion that norms can be chosen between in this manner may in itself be problematic. How can the need for consolidation in order to avoid confusion be balanced with the need for diversity in order to prevent a 'dictatorship of norms'? The answer could be for norms to be subject to periodic review, thereby enabling new circumstances and issues to be taken into account. Whether this would be seen to compromise their moral authority would depend on whether norms are believed to derive from *a priori* values or to be in a constant state of evolution.

## **8.2 IMPLICATIONS FOR GENETICS AND BIOETHICS GOVERNANCE**

Chairman Sader, at the June 2005 meeting of government experts charged with finalising the draft UDBHR, made the following statement:

A bioethics-related event makes the international headlines nearly every week. It is a difficult topic. As we have all seen, there have been deep divisions in other meetings on specific bioethics issues. There are points of divergence within individual countries too. For this reason, it is doubly important for us to give a clear signal that we are capable of reaching agreement on important issues. If we do so, the declaration will be proof that multilateralism works, and that will be a boon to our Organization.<sup>5</sup>

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<sup>5</sup> UNESCO, "Second Session of the Intergovernmental Meeting of Experts: Final Report," Annex III, 1.



TJCB, in its final publication on the proposed GGI, wrote:

The global public goods characteristics of genomics knowledge inevitably raise issues about access to this emerging resource. This will surely test our skills in the evolution and management of *international relations*, foreign policy, regulation and intellectual property rights.<sup>6</sup> (italics added)

Do the UNESCO declarations indeed prove that multilateralism works and thus enhance the legitimacy of their parent organisation? The answer to this question, as shown in 8.1, is at best only a qualified yes. Could the GGI, if established, represent a sufficiently fresh take on international relations that the problems faced by UNESCO might be avoided, thus harnessing the potential advantages of genetic research for all those who stand to benefit from them?

Despite TJCB's emphasis on the urgency with which the 'genomics divide' must be closed, after four years its plans for the GGI network (as an entity<sup>7</sup>) have not yet come to fruition and perhaps never will do. Fieldwork in Kenya and South Africa in late 2005 and early 2006 showed that such a network could prove popular among stakeholders in genetics and bioethics, however. To reiterate a point made in Chapter 7, TJCB's final publication on the GGI acknowledged that the proposed network would have to work alongside existing organisations. If the GGI could be built around the UNESCO declarations, rather than parallel to them, this might facilitate their implementation and avoid unnecessary duplication of both norms and functions. Combining the formal structure of UNESCO with that of a more informal network in this way would encourage high quality discussion within a framework of procedural fairness, thus mitigating the potential for interest-based bargaining and unequal power relations. (The latter might be further abated if measures could be taken to encourage developing countries to play a greater role in deliberations; see 7.2 for suggestions.) The inclusion of those non-state actors who might put the declarations' norms into practice, such as geneticists, ethicists

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<sup>6</sup> Dowdeswell *et al*, op cit, 135.

<sup>7</sup> Some of the activities of TJCB are akin to those proposed for the GGI. A specific network entitled 'Global Genomics Initiative' has not been established, however. Possible reasons why this is the case are discussed in more detail in the recommendations for further research (see 8.3).

and representatives from civil society and industry, would be crucial to the legitimacy of such an endeavour. This could be effected should the network attract a diverse membership, as originally intended. As a united force, UNESCO and the GGI could help to address some of the genetics and bioethics issues highlighted in 6.3.2, namely intellectual property rights, community engagement, social responsibility, benefit sharing and capacity building. Their capacity in this regard would depend significantly on the extent of their funding.

It might be that government officials who are or have been connected with the UNESCO Bioethics Programme, through representing their countries at negotiations or other activities, could work to bring this diverse membership on board. This would have the added bonus of improving relations between state and non-state actors at national level (as 5.2.2 demonstrated is necessary in Kenya and South Africa). It would also be essential for these officials to liaise with their counterparts in related areas of government (perhaps health, research, technology, innovation or education), to prevent an uncoordinated implementation of the declarations around genetic and biomedical research. More broadly, in order for other aspects of the declarations (which have been beyond the scope of this thesis) to also be taken up coherently, it would be necessary for those concerned with research to cooperate with those in the medical and environmental sectors. What this describes is in fact something akin to cosmopolitan democracy's 'array of fora', with points of communication and coordination within and between layers and issues. Some commentators have dismissed this ambitious project as being too long-term to be of use, which if true would mean such a system could prove unachievable. On the other hand, if a multilayered network on genetics and biomedical research ethics could be successfully convened around the UNESCO declarations and subsequently start to make connections with those working in related areas, this might constitute one of Archibugi's "little steps forward" on the road to cosmopolitan democracy.<sup>8</sup>

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<sup>8</sup> Archibugi, "Cosmopolitan Democracy and its Critics," 465-666.



### 8.3 RECOMMENDATIONS FOR FURTHER RESEARCH

This thesis has been necessarily limited in its scope by what can realistically be achieved within the time and funding constraints of a doctoral project. There are several ways in which further research on the issues raised within it could be pursued, empirically and theoretically. Why the GGI has not been established as planned, for instance, is worthy of investigation. It may be that TJCB decided that such a network was not needed after all, given the already existing global initiatives on genetics and bioethics, or that it met with resistance from those who see genomics as a distraction from the root causes of inequalities of health, or that funding and resources were insufficient. These suggestions are merely speculative, however. To determine whether they are correct, or to uncover other possible explanations, there are a number of avenues of inquiry that could be explored. These would begin at TJCB itself, but could also include its funders or others known to have connections with the centre, such as those at GRaPH-Int (see below). Failed networks can be difficult to investigate, because of an understandable reluctance on the part of those involved to revisit what went wrong. The subsequent lack of research on this aspect of networks would make the GGI a particularly interesting study, if it proved possible.<sup>9</sup> The results might have implications beyond genetics and bioethics, if the GGI's failure to develop proved to be because of flaws in the networked governance model adopted rather than factors connected with the particular context. In this regard it might be helpful to examine other networks and projects in related areas, both science- and policy-based, such as the Human Epigenome Project, the Genographic Project, MalariaGEN and GRaPH-Int. These aim, respectively, to identify and catalogue common epigenetic markers in the human genome, to gather genetic samples from indigenous peoples, to analyse variable susceptibility to malaria across human genetic populations and to promote public health genomics.<sup>10</sup>

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<sup>9</sup> Yanacopulos, "Researching Transnational Advocacy Networks," 48-49.

<sup>10</sup> See [www.epigenome.org](http://www.epigenome.org), [www3.nationalgeographic.com/genographic](http://www3.nationalgeographic.com/genographic), [www.malariagen.net](http://www.malariagen.net) and [www.graphint.org](http://www.graphint.org).

With regard to the declarations, Kenya and South Africa are but two of the 190 odd member states of UNESCO, hence any judgement as to how international norms translate to the national level can only be extrapolated to a limited degree. It would thus be enormously profitable to conduct similar field-based analyses in other countries, developing and developed. With particular reference to Africa, further research could explore whether the experiences of other states in negotiating and implementing the declarations have been similar or otherwise to those of Kenya and South Africa. Those states with different philosophical and political backgrounds, in the francophone and lusophone regions, for example, may have had quite different experiences, with possible implications for the universality of norms. The thesis has taken a primarily pragmatic angle on this issue, in terms of how purportedly universal principles are contextualised at national level. It has not come to a conclusion on the point at which these principles, as a “foundation for humanity’s response to the ever-increasing dilemmas and controversies that science and technology present for humankind,” are in fact pluralised, if there is variation in how they are applied.<sup>11</sup> Deeper reflection on the nature of universality in this context would require the input of trained bioethicists and philosophers. This highlights, then, the need for a cross-disciplinary approach to the analysis of international bioethics instruments.

In terms of approaches to global governance, the thesis has highlighted several issues worthy of further consideration. Concerning the relative influence of developed and developing countries in international fora, how equal participation can be encouraged, in terms of attendance, size, and expertise of delegations, needs to be examined. At a broader level, the power differentials often observed during negotiations are symptomatic of wider inequalities, which ultimately need to be eradicated rather than mitigated. The role of experts and interest groups in international deliberations is also subject to ongoing debate. What contribution they should make relative to democratically elected officials or government appointed representatives, on what grounds they should be selected as

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<sup>11</sup> UDBHR, Preamble.



legitimate voices and by whom these decisions should be made are all hard questions, particularly for broad-ranging, global problems. The solutions may lie partly in multilayered governance, but this carries its own dilemmas, such as whether a lattice or array of fora can be managed coherently and how new forms of governance can be integrated with old ones. Finally, the thesis corroborates what some regime theorists have been arguing for decades, that more research in domestic spheres is required. Specifically, the extent to which networks at the national level might enable international instruments to be implemented more effectively, particularly those concerning cross-cutting issues, should be explored further. In this project it has been possible to begin to investigate these themes through particular approaches to global governance, partly because the plans for one of the mechanisms under investigation, the proposed GGI, are based on the networked governance models of Rischard and Slaughter. Scholars should take note when international relations theories are applied in this manner by those outside the field, as such instances provide 'real-life' test cases.

#### **8.4 CONCLUDING REMARKS**

If the potential of human genetic and biomedical research to reduce inequalities of health between North and South is to be fully realised, how this research is governed at both international and national levels must improve within a broader context of global change, such that everyone can enjoy their full political, social and economic rights, regardless of where they live. It is hoped that this thesis' theoretical and empirical contributions to knowledge about global governance will be of some small use to the people engaged in various ways in determining the best means to achieve this change: firstly, those involved in genetics and bioethics in Kenya and South Africa; secondly, those at UNESCO, TJCB and other relevant international bodies; and thirdly, those dedicated to progressing both explanatory and normative approaches to global governance within the field of international relations.

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## **APPENDIX 1: CITED ARTICLES FROM THE THREE UNESCO DECLARATIONS**

The declarations can be viewed in full at [www.unesco.org/bioethics](http://www.unesco.org/bioethics).

### **Universal Declaration on the Human Genome and Human Rights**

11 November 1997

#### **Article 1**

The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

#### **Article 4**

The human genome in its natural state shall not give rise to financial gains.

#### **Article 5**

- (a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law.
- (d) In the case of research, protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines.
- (e) If according to the law a person does not have the capacity to consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition, subject to the

conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights.

#### **Article 7**

Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law.

#### **Article 8**

Every individual shall have the right, according to international and national law, to just reparation for any damage sustained as a direct and determining result of an intervention affecting his or her genome.

#### **Article 12**

(a) Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.

(b) Freedom of research, which is necessary for the progress of knowledge, is part of freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.

#### **Article 16**

States should recognize the value of promoting, at various levels, as appropriate, the establishment of independent, multidisciplinary and pluralist ethics committees to assess the ethical, legal and social issues raised by research on the human genome and its applications.



### **Article 17**

States should respect and promote the practice of solidarity towards individuals, families and population groups who are particularly vulnerable to or affected by disease or disability of a genetic character. They should foster, inter alia, research on the identification, prevention and treatment of genetically based and genetically influenced diseases, in particular rare as well as endemic diseases which affect large numbers of the world's population.

### **Article 18**

States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

### **Article 19**

(a) In the framework of international co-operation with developing countries, states should seek to encourage measures enabling:

- (i) assessment of the risks and benefits pertaining to research on the human genome to be carried out and abuse to be prevented;
- (ii) the capacity of developing countries to carry out research on human biology and genetics, taking into consideration their specific problems, to be developed and strengthened;
- (iii) developing countries to benefit from the achievements of scientific and technological research so that their use in favour of economic and social progress can be to the benefit of all;
- (iv) the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine to be promoted.

(b) Relevant international organizations should support and promote the initiatives taken by states for the above-mentioned purposes.

#### **Article 20**

States should take appropriate measures to promote the principles set out in the Declaration, through education and relevant means, inter alia through the conduct of research and training in interdisciplinary fields and through the promotion of education in bioethics, at all levels, in particular for those responsible for science policies.

#### **Article 21**

States should take appropriate measures to encourage other forms of research, training and information dissemination conducive to raising the awareness of society and all of its members of their responsibilities regarding the fundamental issues relating to the defence of human dignity which may be raised by research in biology, in genetics and in medicine, and its applications. They should also undertake to facilitate on this subject an open international discussion, ensuring the free expression of various sociocultural, religious and philosophical opinions.

#### **Article 22**

States should make every effort to promote the principles set out in this Declaration and should, by means of all appropriate measures, promote their implementation.

#### **Article 23**

States should take appropriate measures to promote, through education, training and information dissemination, respect for the above-mentioned principles and to foster their recognition and effective application. States should also encourage exchanges and networks among independent ethics committees, as they are established, to foster full collaboration.



## **International Declaration on Human Genetic Data**

16 October 2003

### **Article 6**

(a) It is ethically imperative that human genetic data and human proteomic data be collected, processed, used and stored on the basis of transparent and ethically acceptable procedures. States should endeavour to involve society at large in the decision-making process concerning broad policies for the collection, processing, use and storage of human genetic data and human proteomic data and the evaluation of their management, in particular in the case of population-based genetic studies. This decision-making process, which may benefit from international experience, should ensure the free expression of various viewpoints.

(b) Independent, multidisciplinary and pluralist ethics committees should be promoted and established at national, regional, local or institutional levels, in accordance with the provisions of Article 16 of the Universal Declaration on the Human Genome and Human Rights. Where appropriate, ethics committees at national level should be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic data, human proteomic data and biological samples. They should also be consulted concerning matters where there is no domestic law. Ethics committees at institutional or local levels should be consulted with regard to their application to specific research projects.

(c) When the collection, processing, use and storage of human genetic data, human proteomic data or biological samples are carried out in two or more States, the ethics committees in the States concerned, where appropriate, should be consulted and the review of these questions at the appropriate level should be based on the principles set out in this Declaration and on the ethical and legal standards adopted by the States concerned.

## **Article 8**

(b) When, in accordance with domestic law, a person is incapable of giving informed consent, authorization should be obtained from the legal representative, in accordance with domestic law. The legal representative should have regard to the best interest of the person concerned.

(c) An adult not able to consent should as far as possible take part in the authorization procedure. The opinion of a minor should be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity.

## **Article 18**

(a) States should regulate, in accordance with their domestic law and international agreements, the cross-border flow of human genetic data, human proteomic data and biological samples so as to foster international medical and scientific cooperation and ensure fair access to these data. Such a system should seek to ensure that the receiving party provides adequate protection in accordance with the principles set out in this Declaration.

(b) States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning human genetic data and human proteomic data and, in that regard, to foster scientific and cultural cooperation, particularly between industrialized and developing countries.

(c) Researchers should endeavour to establish cooperative relationships, based on mutual respect with regard to scientific and ethical matters and, subject to the provisions of Article 14, should encourage the free circulation of human genetic data and human proteomic data in order to foster the sharing of scientific knowledge, provided that the principles set out in this Declaration are observed by the parties concerned. To this end, they should also endeavour to publish in due course the results of their research.



## **Article 19 – Sharing of benefits**

(a) In accordance with domestic law or policy and international agreements, benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community. In giving effect to this principle, benefits may take any of the following forms:

- (i) special assistance to the persons and groups that have taken part in the research;
- (ii) access to medical care;
- (iii) provision of new diagnostics, facilities for new treatments or drugs stemming from the research;
- (iv) support for health services;
- (v) capacity-building facilities for research purposes;
- (vi) development and strengthening of the capacity of developing countries to collect and process human genetic data, taking into consideration their specific problems;
- (vii) any other form consistent with the principles set out in this Declaration.

(b) Limitations in this respect could be provided by domestic law and international agreements.

## **Article 23**

(a) States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with the international law of human rights. Such measures should be supported by action in the sphere of education, training and public information.

(b) In the framework of international cooperation, States should endeavour to enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge concerning human genetic data and the related know-how.

## **Article 24**

In order to promote the principles set out in this Declaration, States should endeavour to foster all forms of ethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about human genetic data. These measures should aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large. In this regard, States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

## **Article 25**

The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out therein. On a collaborative basis, the two Committees should be responsible for its monitoring and for the evaluation of its implementation, *inter alia*, on the basis of reports provided by States. The two Committees should be responsible in particular for the formulation of any opinion or proposal likely to further the effectiveness of this Declaration. They should make recommendations in accordance with UNESCO's statutory procedures, addressed to the General Conference.



# **Universal Declaration on Bioethics and Human Rights**

19 October 2005

## **Article 2**

The aims of this Declaration are:

(a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;

## **Article 6**

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

## **Article 7**

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent.

Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and

compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

### **Article 8**

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

### **Article 12**

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

### **Article 14**

1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.

2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:

- (a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;
- (b) access to adequate nutrition and water;
- (c) improvement of living conditions and the environment;
- (d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;



(e) reduction of poverty and illiteracy.

## **Article 15**

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

- (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
- (b) access to quality health care;
- (c) provision of new diagnostic and therapeutic modalities or products stemming from research;
- (d) support for health services;
- (e) access to scientific and technological knowledge;
- (f) capacity-building facilities for research purposes;
- (g) other forms of benefit consistent with the principles set out in this Declaration.

2. Benefits should not constitute improper inducements to participate in research.

## **Article 18**

2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.

3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

## **Article 19**

Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

- (a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;

(d) foster debate, education and public awareness of, and engagement in, bioethics.

## **Article 20**

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

## **Article 21**

2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.

3. Transnational health research should be responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.

4. When negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation.

## **Article 22**

1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information.

2. States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, as set out in Article 19.



### **Article 23**

1. In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.

### **Article 24**

1. States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.
2. Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.

### **Article 25**

1. UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).
2. UNESCO shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.

## **APPENDIX II: INTERVIEWS**

The descriptions vary in specificity according to the degree of anonymity requested by each participant. Where some codes appear missing, either they were not assigned or no data from the interviews have been used.

| <b>Code</b> | <b>Location and date</b> | <b>Description or affiliation</b>  |
|-------------|--------------------------|--|
| K_01        | Nairobi, 4.10.05         | Kenyan representative at the UNESCO IGE meetings, April and June 2005                  |
| K_02        | Nairobi, 5.10.05         | Social and Human Sciences Committee of the Kenya National Commission for UNESCO        |
| K_03        | Nairobi, 5.10.05         | As above   |
| K_04        | Nairobi, 6.10.05         | African Technology Policy Studies  |
| K_05        | Kilifi, 11.10.05         | KEMRI-Wellcome Trust Collaborative Programme   |
| K_06        | Kilifi, 11.10.05         | As above   |
| K_07        | Kilifi, 11.10.05         | As above   |
| K_08        | Kilifi, 11.10.05         | As above   |
| K_09        | Kilifi, 12.10.05         | As above   |
| K_10        | Nairobi, 13.10.05        | African Biotechnology Stakeholders Forum   |
| K_11        | Nairobi, 19.10.05        | Inter Region Economic Network  |
| K_12        | Nairobi, 12.10.05        | Attendee at the 2002 TJCB-African Centre for Technology Studies genomics policy course |
| K_13        | Nairobi, 24.10.05        | Natural Sciences Committee of the Kenya National Commission for UNESCO                 |
| K_14        | Nairobi, 26.10.05        | Biosafety News   |
| K_15        | Nairobi, 31.10.05        | World Health Organization, Kenya office  |
| K_16        | Nairobi, 1.11.05         | Kenya National Commission for UNESCO   |
| K_17        | Nairobi, 2.11.05         | Member of a research ethics committee  |



| <b>Code</b> | <b>Location and date</b> | <b>Description or affiliation</b>                                  |
|-------------|--------------------------|--|
| K_18        | Nairobi, 3.11.05         | Advisor on national biosafety policy                               |
| K_19        | Nairobi, 3.11.05         | Member of a research ethics committee                              |
| K_20        | Nairobi, 7.11.05         | Kenya National Biosafety Committee                                 |
| K_21        | Nairobi, 5.10.05         | Ministry of Education, Science and Technology                      |
| K_22        | Nairobi, 7.10.05         | African Technology Policy Studies                                  |
| K_23        | Kilifi, 12.10.05         | KEMRI-Wellcome Trust Collaborative Programme                       |
| K_24        | Nairobi, 14.10.05        | Africa Centre for Technology Studies                               |
| K_25        | Nairobi, 25.10.05        | Member of two research ethics committees                           |
| K_26        | Nairobi, 25.10.05        | Geneticist at a university   |
| K_27        | Nairobi, 1.11.05         | Ministry of Health   |
| K_29        | Nairobi, 21.11.05        | Geneticist at a research institute                                 |
| K_30        | Nairobi, 8.11.05         | Ministry of Foreign Affairs  |
| SA_02       | Cape Town, 28.3.06       | South African National Bioinformatics Institute                    |
| SA_03       | Cape Town, 28.3.06       | Geneticist at a university   |
| SA_04       | Cape Town, 29.3.06       | Division of Human Genetics, University of Cape Town                |
| SA_06       | Cape Town, 30.3.06       | Senior member of a commercial genetics company                     |
| SA_07       | Cape Town, 30.3.06       | South African National Bioinformatics Institute                    |
| SA_08       | Stellenbosch, 31.3.06    | Centre for Applied Ethics, University of Stellenbosch              |
| SA_09       | Cape Town, 3.4.06        | International Research Ethics Network for Southern Africa (IRENSA) |
| SA_10       | Cape Town, 10.4.06       | Member of a research ethics committee                              |
| SA_11       | Cape Town, 10.4.06       | Africa Genome Education Institute                                  |
| SA_12       | Durban, 5.4.06           | Centre for HIV/AIDS Networking                                     |

| <b>Code</b> | <b>Location and date</b> | <b>Description or affiliation</b>  |
|-------------|--------------------------|--|
| SA_13       | Durban, 7.4.06           | LIFElab  |
| SA_14       | Pietermaritzburg, 6.4.06 | School of Philosophy and Ethics, University of KwaZulu-Natal                 |
| SA_15       | Pietermaritzburg, 6.4.06 | South African Research Ethics Training Initiative (SARETI)                   |
| SA_16       | Johannesburg, 10.4.06    | Bioethics Division, University of the Witwatersrand                          |
| SA_17       | Unspecified              | An academic in a senior position in bioethics at a health sciences faculty   |
| SA_18       | Johannesburg, 10.4.06    | Geneticist at a university   |
| SA_19       | Johannesburg, 12.4.06    | Human Research Ethics Committee (Medical), University of the Witwatersrand   |
| SA_20       | Johannesburg, 12.4.06    | Geneticist at a university   |
| SA_21       | Johannesburg, 13.4.06    | As above   |
| SA_23       | Johannesburg, 13.4.06    | South African representative at the UNESCO IGE meeting, June 2005            |
| SA_24       | Pretoria, 24.4.06        | Geneticist, research ethics committee member and ethics lecturer             |
| SA_25       | Pretoria, 19.4.06        | Senior member of an independent ethics institute                             |
| SA_26       | Pretoria, 20.4.06        | Department of Science and Technology   |
| SA_27       | Pretoria, 20.4.06        | Geneticist at a research institute   |
| SA_28       | Pretoria, 21.4.06        | Advisor on national innovation policy  |
| SA_29       | Pretoria, 21.4.06        | Public Understanding of Biotechnology programme                              |
| SA_30       | Pretoria, 25.4.06        | Geneticist at a university   |
| SA_31       | Pretoria, 25.4.06        | Department of Science and Technology   |
| SA_32       | Pretoria, 1.5.06         | Advisor on national innovation policy  |
| SA_33       | Pretoria, 26.4.06        | Council for Scientific and Industrial Research                               |
| SA_34       | Pretoria, 28.4.06        | National Research Foundation   |
| SA_35       | Pretoria, 2.5.06         | Faculty of Health Sciences Research Ethics Committee, University of Pretoria |



| <b>Code</b> | <b>Location and date</b> | <b>Description or affiliation</b>                         |
|-------------|--------------------------|---|
| SA_37       | By telephone, 11.7.06    | Center for the AIDS Programme of Research in South Africa |
| UK_01       | By telephone, 5.9.05     | Attendee at the UNESCO IGE meetings, April and June 2005  |
| UK_02       | London, 30.11.05         | As above  |
| F_01        | Paris, 29.8.05           | UNESCO Bioethics Programme secretariat                    |
| F_02        | Paris, 30.8.05           | Attendee at the UNESCO IGE meetings, April and June 2005  |